

An empirical ethics analysis of breast cancer screening in Australia

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Candidate's declaration

I, Lisa Parker, hereby declare that the work described in this thesis is my own. I am the principal researcher of all work contained in this thesis, including work conducted in association with my PhD supervisors and other co-authors. This thesis does not contain written or published materials prepared by others except where acknowledged within the text and has not been submitted to any other university or institution as a part or whole requirement for any higher degree.

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Abstract

Breast screening is a large and important public health program that attracts controversy and disagreement. While there are many supporters for breast screening, there are others, including people with expertise and experience in breast screening, who disagree with at least some of the common breast screening policies and practices. Disagreement persists despite a large evidence base around breast screening. I sought to examine how opinions were formed amongst people who have been influential in developing breast screening policy and practice in Australia, and the role of values in their reasoning. I used an empirical ethics approach, combining empirical study with theoretical analysis. For my empirical research I interviewed Australian “experts”: individuals with expertise and influence in breast screening, including participants from a range of professional roles and experience related to breast screening. I questioned these experts about their views on breast screening with a particular interest in determining how these views were formed. I found that participants draw on values as well as evidence when talking and reasoning about breast screening. The group expressed a range of interpretations and priority levels for each value. I explored several aspects of breast screening in depth to examine these findings in more detail, focusing in turn on the topics of overdiagnosis, communication with consumers, and socially embedded concepts in breast screening. In each of these subjects I found that experts’ disagreements were based, at least in part, upon differences in the way they understood and prioritised certain important values. Experts did not always reflect on the role of values in shaping their views on breast screening, and did not necessarily recognise differences in how any given value was conceptualised. I drew upon these findings to consider decision making in breast screening policy and practice and explore ways of managing values based conflict in

breast screening. In the Discussion I suggest that there be explicit acknowledgement of the role of values in shaping views about breast screening, and that values should be openly discussed and debated. I provide practical guidance about formats that such discussions might take. I conclude that values play an important but often unrecognised role in shaping breast screening policy and practice, and propose that there be regular review of such values and the ways in which they relate to breast screening, in order to deliver breast screening in the most ethically sound manner.

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List of special terms and abbreviations

ACS: American Cancer Society (advocacy organisation for cancer control).

Aggregate benefits: In public health, aggregate benefits of a program or policy consist of all of the benefits experienced by individuals added up; for example, in breast screening, aggregate benefits are the sum of benefits experienced by (a few) individuals as a result of participating in screening. (See also: *corporate benefits*).

ASE: Attitude-Social influence–Efficacy model for explaining human behaviour.

Autonomy: An autonomous person is one who sees herself as in being charge of her own life; believes this to be appropriate; and has the freedom, opportunity, skills and capacities required to make choices, take action, and live in a manner that is consistent with her sense of who she is.

BCDDP: Breast Cancer Detection and Demonstration Project that occurred in the USA in the 1970s as a way of demonstrating the feasibility and benefits of breast screening.

Breast cancer: A neoplasm in the breast containing abnormal cells that usually have characteristics of cells from the milk gland ducts. Breast cancer may or may not spread beyond the milk glands (invasive or in situ disease respectively. (See also: *carcinoma in situ* and *DCIS*).

Carcinoma in situ: In the breast, carcinoma in situ refers to a cancerous growth which is confined to the duct system and has not spread (“invaded”) into adjacent tissues. (See also: *DCIS* and *LCIS*). Carcinoma in situ is synonymous with in situ carcinoma and (for the purposes of this thesis) in situ cancer, and in situ disease.

CC: Craniocaudal - from the head to the tail. In the context of mammography a craniocaudal breast x-ray is a top-to-bottom view, i.e. taken after compressing the breast from top to bottom (see also: *MLO*).

Citizens’ jury (also known as **community jury**): A deliberative democratic method whereby a group of 12-24 individuals are recruited to meet for a period ranging from 1-7 days and produce a set of recommendations or a decision on one or more defined questions. The jury receives information and evidence, cross-examines witnesses, and then deliberates on the issue at hand. (See also: *deliberative democracy methods*).

Core biopsy: A procedure for obtaining a small sliver of body tissue using a wide calibre needle. The tissue is processed and examined under a microscope for diagnostic purposes. (See also: *FNA*).

Corporate benefits: in public health, the corporate benefits of a program or policy are those benefits that occur at the population level only; for example, in breast screening, corporate benefits are the added benefits (beyond aggregative benefits) that accrue to an entire community as a result of breast screening policies and practices. A clear example of a

corporate benefit in public health is the herd immunity that results from achieving a certain vaccination rate in a population. (See also: *aggregate benefits*).

DCIS: Ductal carcinoma in situ. A type of carcinoma in situ in the breast where the cancerous cells have characteristics of cells from the milk gland ducts. The cancerous cells have not spread out of the breast duct. Some DCIS lesions may progress to invasive breast cancer with the potential for metastatic spread and threat to life. DCIS rarely forms a lump but if present, it can often be seen on a mammogram. (See also: *carcinoma in situ*).

Deliberative democratic methods: Ways of engaging citizens in formal iterative dialogue on important and complex problems. The main goal is to use the considered opinions and values of informed members of the public in a policy process; deliberative methods tend to provide participants with information, involve a range of people with diverse perspectives, and provide opportunities for reflection, critique and discussion. The two-way process of information exchange distinguishes deliberative democratic methods from other methods of communication with the public, which are dominated by one or other party informing the other (e.g. consumer information pamphlets, public polling). Policies that incorporate public opinions obtained through deliberative democracy methods can be more legitimate, justifiable and feasible than those that do not. Different deliberative democratic methods include citizens' juries, consensus conferences, study circles, and citizens' assemblies. (See also: *citizens' jury*).

Distributive justice: This concept is about fairness, including fairness of opportunity (e.g. the opportunity for all individuals to pursue good health), and fairness of outcome (e.g. everyone in a society achieving at least a basic or threshold level of good health).

EBM: Evidence based medicine.

Empirical ethics: An emerging methodology that combines theoretical ethics analysis with empirical research. A range of different ways for combining theory and empirical work have been described. This thesis uses an approach that assumes theory and data interact with each other, such that theory can direct empirical research, and empirical results can inform normative conclusions.

FNA: Fine needle aspiration – a biopsy procedure for obtaining a sample of cells from bodily tissue or fluid using a small calibre needle. Cells are then examined under a microscope for diagnostic purposes. (See also: *core biopsy*).

HBM: Health Belief Model for explaining human behaviour.

HIP: Health Insurance Plan. A New York based health insurance organisation that was involved in the first RCT on breast screening.

HIV: Human immunodeficiency virus.

IDM: Informed decision making. In healthcare, informed decision making implies that patients or consumers have information and understanding about their health conditions and the nature and purpose of available interventions, including benefits, harms and risks of choosing to participate or not participate. It generally requires meaningful dialogue with healthcare workers, and the opportunity for people to make choices that are in their own best interests.

LCIS: Lobular carcinoma in situ. An uncommon type of carcinoma in situ in the breast where the cancerous cells have characteristics of cells from the milk gland lobules. The cancerous cells have not spread out of the breast lobule. LCIS may eventually progress to become invasive cancer in a minority of women. It is also regarded as an indicator that a woman may develop invasive breast cancer elsewhere in either breast.

Lead time bias: The bringing forward in time of a cancer diagnosis through screening: even if the natural history of a cancer is completely fixed, bringing the diagnosis forward in time will give an incorrect illusion of improved survival for those diagnosed through screening.

Length time bias: The tendency of screening programs to pick up naturally slower growing cancers (some of which may never even have come to clinical attention without screening) and which will necessarily have a better prognosis - again, giving an incorrect illusion of screen-related benefit.

MLO: Mediolateral oblique. An MLO mammogram provides an angled side-to-side view of the breast, i.e. taken after compressing the breast along a line from the armpit towards the navel. (See also: *CC*).

NCI: National Cancer Institute. A U.S. government cancer research and training organisation.

Neoplasm: A new and abnormal mass of tissue resulting from the uncontrolled multiplication of cells. The pathological process that results in a neoplasm is called neoplasia. (See also: *carcinoma in situ*).

NHMRC: National Health and Medical Research Council. An Australian government medical research organisation.

NIH: National Institutes of Health. A U.S. government department in charge of medical research.

Non-maleficence: The principle of non-maleficence imposes an obligation not to inflict harm on others. In healthcare, non-maleficence demands that healthcare workers avoid inflicting harm on patients or consumers.

Overdetection: A health related finding in a person, most likely occurring through the use of testing technology, which does not produce a net benefit for that person. (See also: *overdiagnosis*).

Overdiagnosis: The diagnosis of a condition in a person, where that diagnosis would be considered correct, but it does not produce a net benefit for that person; for example, diagnosis through screening of an indolent breast cancer that would never progress, or progress so slowly that, without screening, it would not have come to the attention of the individual in her lifetime. (See also: *overdetection*).

Overmedicalisation: Altering the meaning or understanding of experiences, so that health-related findings are re-interpreted as medical problems requiring medical treatment, without net benefit to patients or citizens.

Pathophysiology: The processes and changes associated with or resulting from disease.

Procedural justice: Fairness in decision making; for example, in breast screening, procedural justice might require ensuring that all relevant stakeholders are included, that decisions are made for good reasons, that decisions are open to revision if new evidence or arguments emerge, and that biases and vested interests are minimised in order to ensure decisions are made in the best interests of the public. (See also: *distributive justice*).

Prognosis: A medical prediction of the likely outcome of a person's disease or health status.

QALYs: Quality adjusted life years. A measure of disease burden, including both quantity and quality of life. It is used in health economics to evaluate and compare the cost-efficiency of healthcare interventions.

Radio-opaque: Not penetrable by radiation, therefore visible as white on x-ray.

Radiolucent: Penetrable by radiation, therefore not visible on x-ray.

RCT: Randomised controlled trial.

Reciprocity: Returning a favour that is done to you, sharing with others in the carrying of public burdens, and supporting and compensating those who carry the heaviest burdens.

SDM: Shared decision making. This term describes a process of communication between clinicians and patients to discuss evidence, personal preferences, and other relevant matters when making decisions about healthcare.

Solidarity: ‘Pulling together’ towards a common (collective) cause on the understanding that there is mutual respect and obligation between members of a community and a sharing of burdens and threats.

Technological imperative: A rule or belief that if a new technology exists, we need it. That is, we tend to believe that because we have the technology available, we must use it, sometimes before it has been proven safe or effective.

Thermography: A thermal breast imaging technique that produces heat pictures of the breast that may be useful in diagnosing disease. It is not widely available as there is limited evidence to support its usefulness.

TRA: Theory of Reasoned Action model for explaining human behaviour.

Transparency: In the context of public health this term is often used to describe the full and honest disclosure of how, and by whom, decisions and policies are made. This includes the disclosure of possible vested interests amongst policy makers and advisors.

USPSTF: United States Preventive Services Task Force. An independent panel of medical and public health experts that regularly and systematically reviews the effectiveness of preventive services, and issues recommendations for practice.

Values: In ethics, values are one's principles or standards of behaviour; they denote one's judgement of what is important in life.

Contributions, publications, and presentations

Associate Professor Stacy Carter was my primary supervisor and Associate Professor Lucie Rychetnik was my associate supervisor. Both made conceptual and editorial contributions to the work contained in this thesis and are co-authors on some of the resulting publications.

Several chapters in this thesis (Chapters 2, 5, 6, 7 and 8) contain material that is published with the following citation details:

Parker LM, Carter SM. Social and ethical considerations in breast cancer screening. In: Houssami N, Miglioretti D, editors. Breast cancer screening: the scientific evidence. London, UK: Elsevier; 2016. p. 347-374.

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Parker LM, Rychetnik L, Carter S. Framing overdiagnosis in breast screening: a qualitative study with Australian experts. *BMC Cancer*. 2015;15(1):606.

Parker LM, Rychetnik L, Carter SM. The role of communication in breast cancer screening: a qualitative study with Australian experts. *BMC Cancer*. 2015;15(1):741.

Parker LM, Carter SM. The role of socially embedded concepts in breast cancer screening: an empirical study with experts. *Public Health Ethics*. 2016;phw01.

The specific contributions of the co-authors of these manuscripts are as follows: LP wrote the first and all subsequent drafts on all of these manuscripts. SC made conceptual and editorial contributions to all papers. LR made conceptual contributions to manuscripts for publications (b), (c) and (d) and made editorial contributions to publication (e).

I have also made several oral presentations that draw on material from this thesis. The presentation details are as follows:

Parker L, Carter S, Rychetnik L. Should shared decision making be the aim in breast cancer screening? Joint Conference of the International Shared Decision-Making group and the International Society for Evidence Based Health Care (ISDM/ISEHC); 19-22 July; Sydney, Australia 2015.

Parker L, Rychetnik L, Carter S. Reciprocity and solidarity in breast cancer screening: an empirical study with Australian experts. Conference of the Australasian Association of Bioethics and Health Law (AABHL); 25-28 June; Wellington, New Zealand 2015.

Parker L. Ethical issues in breast cancer screening. STEP Seminar Series at the School of Public Health, University of Sydney; 30 June 2013.

Parker L. Breast cancer screening: scientific, social and political influences.

Lunchtime Seminar Series at the School of Public Health and Community Medicine,
University of New South Wales; 15 May 2013.

Parker L. Breast cancer screening by mammography. Conversation Seminar Series
at the Centre for Values, Ethics and the Law in Medicine, School of Public Health,
University of Sydney; 9 May 2013.

The final editorial authority remains my own.

Lisa Parker



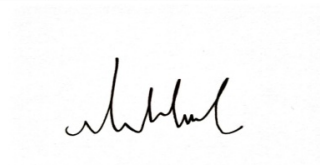
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For Andrew, Anneka, Greta and Finn, with all my love

Preface and thesis overview

This thesis describes an empirical ethics study of the views of Australians with experience at working in a breast screening related field, and who exerted an influence on breast screening policy and/or practice. My interest in ethics within breast cancer screening was stimulated by my clinical practice as a trainee breast radiologist/physician in an NHS breast screening unit in the United Kingdom. I noticed mixed attitudes towards breast screening amongst my clinical colleagues, some of them being very supportive of the program, and others being sceptical of one or more aspects of the work. Both groups appeared to have the best interests of their patients in mind and both cited evidence to support their views. At the same time I was undertaking a Masters Degree in Bioethics, and I began to wonder about the connection between my colleagues' stance on breast screening and their individual views about what was important in medicine, and in life more generally. It appeared to me that disagreements in breast screening might not only be about the evidence, as the published literature had led me to believe, but might be at least partly about values and ethical commitments, implicit or explicit, such as whether an individual was more concerned about delivering (breast screening related) benefit, or avoiding (breast screening related) harm.

A couple of years after this I had the opportunity to participate in a large NHMRC funded project exploring the ethical issues in cancer screening in Australia. I chose to focus on the breast screening arm of that study, while others concentrated on cervical and prostate screening. While my broad research area of ethics in breast cancer screening was shaped by the overarching project goals, I led the development of my specific research questions and

selection of study methods. I pursued an empirical ethics approach, aiming to combine empirical data about this topic with theoretical analysis.

Organisation of thesis

This thesis is arranged into nine chapters, several of which have been published, are in press, or have been submitted for publication and are undergoing review. Each chapter contains its own reference list. Supplementary material accompanying published papers is included at the end of the relevant chapter. Other supplementary material is included in the Appendices.

In **Chapter 1** I present an historical overview of breast screening. I begin in the late 19th century, and discuss the changing model of diseases such as breast cancer, previously thought of as local manifestations of a systemic disease but increasingly understood to be local diseases with the potential for progressive spread and dissemination. I proceed to describe the impact of these new ideas on management of breast cancer, including the concept of early diagnosis and its extension into screening. During the second half of the 20th century, technological advancements made breast screening by mammography possible, and research suggested that it would reduce population breast cancer mortality. Breast screening became widespread throughout the developed world, with Australia introducing a government-funded program in 1991. Over the last 25 years, reviews of the evidence have suggested that the breast cancer mortality reduction attributable to breast screening might be less than previously thought. Recent improvements in treatment might also mean that the window for breast screening to have an effect is smaller. There has been increasing interest in possible harms associated with breast screening, including false positive diagnoses and overdiagnosis.

As a result of all this, there has been public speculation among some breast screening experts about the net benefit of breast screening, although it remains popular with many women and healthcare professionals.

In **Chapter 2** I discuss social and ethical issues relevant to breast cancer screening. I note that as breast screening has become an important public health intervention, its policies and practices have influenced, and been influenced by, social factors and deeply held values. I describe the interaction between breast screening and societal attitudes towards the breast and breast cancer. I discuss changing ideas about health and risk aversion, as well as relevant biomedical paradigms. Breast screening is associated with a strong advocacy movement, political interest and substantial commercial potential; these factors have impacted upon its development and are likely to have an ongoing influence on its future. The ethical issues that are particularly relevant to breast screening include several important principles drawn from healthcare ethics literature. In the second half of this chapter I describe and explain these principles with particular attention to the breast screening context. I cover familiar principles such as: maximising benefits (within resource constraints), minimising harms, respecting autonomy, and just distribution of benefits and burdens. I also write about less widely discussed concepts including: honesty, transparency, procedural justice, reciprocity, and solidarity. This chapter is currently in press within a scholarly book.

In **Chapter 3** I provide a formal review of the broad empirical literature that has explored the role of values in shaping views about breast screening amongst health professionals and the public. I describe how most empirical studies have investigated the views of women, with a few focusing on the views of primary healthcare practitioners, and none specifically looking

at the views of individuals who influence or develop breast screening policies and practices. Within these studies, researchers have tended to focus on the influence of health beliefs about breast cancer, the benefits of breast screening, and personal breast cancer susceptibility. Some researchers have explored the impact of a woman's psychological responses to breast cancer or breast screening on their views about screening. Other researchers have considered the role of values in shaping the views of a woman or practitioner in relation to breast screening. I conclude this chapter by reflecting on the lack of research into the views of influential experts: the people likely to influence breast screening policy and practice. Thus, although expert guidance and guidelines have a significant impact upon women's breast screening opportunities, there is limited understanding about how these individuals formulate their views, including a lack of knowledge about the role of ethical considerations. **The empirical research project described in the remainder of this thesis addresses this gap in the literature.**

In **Chapter 4** I describe the evolution and practice of my research aims and methods. I discuss my commitments to empirical study and, following on from Chapter 3, to exploring the views of breast screening experts. I note my particular interest in the role of ethical considerations in experts' thinking, and in the wider context of decision making for breast screening policy and practice. I go on to describe my methodology, explaining the emerging discipline of empirical ethics that combines empirical research with theoretical analysis, and then discuss the particular empirical and theoretical approaches that I used in my study. I provide a detailed overview of my methods, including selection and sampling of participants, collection and analysis of data. I have placed supporting material in related Appendices. I describe how my study unfolded, including the selection of individual topics for deeper

analysis. I provide information about research ethics and conclude with a description of my subsequent interactions with study participants.

Chapter 5 contains the first published paper derived from my empirical research. In this paper I describe my findings concerning the ethical and epistemological values that breast screening experts expressed when talking about breast screening. I also note the variation in how experts conceptualised values, and in how they prioritised values that were perceived to be in conflict with each other. I describe some of the decision-making difficulties that might result from these variations. I conclude this paper with a recommendation that explicit discussions about values should be a regular part of breast screening review and evaluation, in order to improve understanding between those who hold opposing positions, develop agreements on important aspects of screening, and make ethically sound decisions about policy and practice.

Chapter 6 contains the second published paper from my empirical work. In this paper I focus on the topic of overdiagnosis in breast screening and describe the different ways that experts discussed and framed this concept. I apply framing theory to my analysis, a particularly useful tool to illustrate the variation amongst experts' thinking about multiple aspects of overdiagnosis in breast screening, including: what the problem actually is, likely causes and preferred solutions, and moral judgements about the issue. Some of the frames used by experts were starkly different to one another. Drawing on the empirical evidence reported in this paper, I conclude my report with the suggestion that explicit consideration of the identified frames might be a useful tool for experts and others who are trying to engage

with the topic of overdiagnosis in breast screening, and might promote understanding between those with differing views.

Chapter 7 contains the third published paper relating to my empirical studies. This paper explores the ways that experts viewed the topic of communication with breast screening consumers. I describe how experts held differing opinions on two important topics: the extent to which potential breast screening consumers should be guided to participate in screening, and the depth of information about overdiagnosis that should be provided to women. Combining these findings, I present the range of experts' views about consumer communication, describing them in turn as: "Be screened", "Be screened and here's why", and "Screening is available, please consider whether it's right for you". In the remainder of this paper I explore the ethical values underpinning experts' reasoning behind their views on this specific topic, and, as with the more general paper in Chapter 5, note differences in the ways that experts conceive of and prioritise ethical values. I finish by providing a possible template for how discussions about values might be structured, and reiterating my suggestion that explicit discussion about values should be a regular feature of decision making for breast screening policy and practice.

In **Chapter 8** I include the fourth published paper that draws directly on my empirical results. In this paper I discuss socially embedded concepts, and consider their relevance to breast screening. I suggest that breast screening has characteristics of both clinical medicine and public health, and discuss the implications of this in terms of ethical reasoning about policy and practice. I describe my empirical findings regarding the ways in which Australian breast screening experts use socially embedded concepts when talking about breast screening.

Drawing on both my empirical work and on theoretical arguments, I conclude that socially embedded concepts are relevant to breast screening and should be incorporated in ethical analyses of policy and practice.

Chapter 9 contains a discussion of the overall thesis and my final conclusions. In this chapter I revisit my initial observation that apparently well-meaning experts exhibit varying views about breast screening, and I review the different ways that others have explained and tried to address this situation. A commonly reported explanation is that differing opinions derive from readings and interpretations of the evidence, and I note the diverse range of suggestions about how evidence should be better conducted, communicated or interpreted in order to deliver a message that is more consistent with the epistemological values of the author or authors. A second explanation is that experts' views are influenced by their values, including particular ways of balancing or prioritising values. Ways to manage variance in how people think about values range from suggestions that values should be somehow removed from decision-making (which should, somewhat implausibly, instead rely solely on evidence) to exhortations for explicit debate about contentious values, typically in the context of a specific breast screening related topic such as communication with consumers. I compare and contrast these ideas with my own findings as described in this thesis. While agreeing that ethical considerations are an important part of experts' views about breast screening, I suggest that rather than discussing just one or two values, better understanding and management of experts' disagreements might be gained from a much more substantial engagement with ethics research, theory and practice. I repeat my recommendations to educate experts about the language and concepts in ethics, and to explicitly include discussions about values in breast screening reviews, evaluations, and decision-making

processes. I expand upon my previously described models of how to structure these discussions. I close by recommending research into how, and to what extent, the ethical values of the public should be included in decisions for breast screening policy and practice.

Ethics approval for the empirical arm of this study was gained from the Cancer Institute of New South Wales Population and Health Services Research Ethics Committee [HREC/12/CIPHS/46] and the University of Sydney Human Research Ethics Committee [#15245].

Chapter 1: A biomedical history of breast screening by mammography

1.1 Chapter introduction

There are several topics that provide important background to the research I discuss in this thesis. These topics include: the history of breast screening by mammography; social and ethical considerations relevant to breast screening; the normal breast; the pathology of breast cancer; and current Australian breast screening practices. This chapter outlines the history of breast screening using a biomedical focus, and with a particular spotlight on the Australian context. It is intended to provide context for my empirical study, illuminating the medical and technological background that may have influenced the experts I interviewed. Social considerations are described in **Chapter 2**, along with an introduction to relevant ethical issues. Background information about the normal breast, breast cancer pathology, and breast screening practices is provided in **Appendices 1, 2 and 3** respectively. The literature searching process used for this chapter and for **Chapter 2** is described in **Appendix 4**.

1.2 Historical background – the challenges of breast cancer

Breast cancer has been recognised and recorded as a pathological entity for many millennia, appearing in records as far back as ancient Egypt in 2500-3000 B.C.^{1,2} From these early days, physicians noted that breast cancer would typically declare itself as a breast mass, increasing in size and becoming ulcerated, painful and malodorous. Symptoms of widespread bodily involvement tended to develop later in the disease and death typically occurred within three to four years of the patient noticing the mass. There were infrequent stories of long-term survival (see **Appendix 2** for more detail on breast cancer pathology). Throughout ancient and more modern times, the recommended management for breast cancers has included systemic therapies, such as attention to diet and rest, as well as

treatment of local disease by cauterly, caustic medicines or surgery. Such regimes might temporarily improve a woman's spirits and alleviate her local symptoms but it was widely thought that breast cancer was incurable.¹⁻³

By the 1700s, ideas about sickness and disease were beginning to change. After centuries of accepting that ill-health was predominantly due to a systemic, or whole-of-body problem, a new theory was put forward, suggesting that some diseases, such as cancer, might begin as a local problem.^{1,2} The implication of this was that early local control might sometimes be more effective than systemic treatment. Surgical removal of the breast tumour, along with any obviously diseased tissue in the axilla, became a more common treatment for breast cancer, and seemed to delay breast cancer death in some women.¹⁻⁵ The introduction of anaesthesia in 1846 and aseptic surgical techniques in the 1860s facilitated improvements in surgical experience and technique. Some surgeons began to advise routine removal of the entire breast, and others also advocated for regular excision of axillary glands: there was hope that such treatments might prevent local recurrence altogether, and, if the localised theories about the origin of breast cancer were correct, could result in a complete cure. In 1894, the American surgeon, William Halsted, reported on his treatment successes with an even more extensive operation, something that he recommended for all women with breast cancer.⁶ His technique, variously called a "complete operation", "Halsted mastectomy" or "radical mastectomy", included removal of the entire breast together with the underlying muscles *Pectoralis minor* and *Pectoralis major* and the axillary lymph nodes.^{2(p7),7} It left many women with severe disfigurement and restricted use of the arm, but nevertheless there was widespread enthusiasm for his methods, and optimism that surgery could, if thorough

enough, effect a total cure.¹ From the turn of the 20th century, radical mastectomies became increasingly recommended as the routine treatment for breast cancer.⁴

1.3 The promise of early detection

Although the outlook for most women with breast cancer remained poor, those who presented and were treated for smaller tumours did appear to have better surgical outcomes. It seemed that the best chance of treatment was not only to remove all the local tissues and lymphatics that could be harbouring cancerous cells, but to do so early in the apparently relentless growth pattern of the disease, before cancerous cells spread beyond the immediate area. There were recommendations that surgical removal of local tissues should be performed as soon as possible after presentation, and from the early 1900s, women were encouraged to seek prompt medical attention for breast lumps. Taking this idea even further, women were advised to regularly self-check their breasts and doctors were encouraged to screen asymptomatic women using physical examination, in an attempt to find tiny masses that had not yet declared themselves to the patient.^{1,8} Screening by physical examination certainly did reveal breast lumps in some asymptomatic women, and those women were noted to live longer after diagnosis than women whose breast cancers were diagnosed after symptomatic presentation.⁹ The improved survival time may have been affected by lead time bias but nevertheless enthusiasm for screening increased, and soon progressed to include technological interventions.

Breast x-rays were already being used sporadically to assist with the differential diagnosis of breast lumps, particularly where clinical signs were inconclusive.^{10, 11} The ability of x-rays to

identify impalpable breast lesions was recognised as early as 1913.^{12, 13} Though there was international enthusiasm for breast x-rays in the diagnostic and screening setting, their use was initially limited by the inherent technical differences and challenges associated with radiography of soft tissues compared to bone. The lack of a well defined, standardised technique and dedicated equipment meant that breast x-rays produced unreliable results and were difficult to interpret.^{14, 15} Nevertheless, by the middle of the twentieth century, various centres throughout Australia, United States, Britain and Europe were using breast x-rays as a screening tool and collaborating with other enthusiasts about techniques and technological variables including positioning, breast compression, target-film distance, exposure time, and film type in an effort to improve x-ray quality.^{10, 14}

There were pockets of vocal opposition to the current management strategies of radical surgery and early diagnosis: after decades of radical surgery and “do not delay” campaigning,^{1(p144)} the population breast cancer mortality rate was relatively unchanged.¹⁶ In 1951, American surgeon, Ian MacDonald, suggested that many cancers may run a largely predetermined course, and that the ability of treatment to affect this was limited, an idea termed “predeterminism”.^{17(p450)} According to this model the good prognosis of women with small, localised tumours was at least partly due to inherently slow growth pattern of many of these cancers rather than the extent or timing of the surgery. Conversely, the poor prognosis of women with extensive disease might often be due to the natural, rapid progression of their disease rather than to inadequate or delayed surgical clearance.¹⁸ According to this interpretation, radical surgery might be unnecessarily disabling, and screening was not only largely ineffective for many women but somewhat problematic, as it might lead to exploratory surgery for benign masses, and distracted people from research into new, more

effective treatments.^{1, 19} There was particular concern about allegedly excessive public anxiety arising from promotion of the message that early diagnosis is vital for the management of breast cancer. This general state of high public anxiety was described by the American surgeon, George “Barney” Crile, Jr (1955, cited by Aronowitz^{1(p187)}) as “cancerphobia”.

The idea of predeterminism was only adopted by a minority of professionals.¹ Mainstream medical and public opinion remained focused on the pursuit of earlier and earlier diagnoses on the premise that would be an effective way of addressing the significant mortality rate of this “most frightening disease of women”.^{8, 14(p1104)} In America it was estimated that more than one in 20 women would be diagnosed with breast cancer, about half would die within five years, and most would be dead by 15 years.^{16, 20, 21} The apparent success of cervical screening by the Papanicolaou test in reducing cervical cancer mortality was often discussed, and stimulated efforts to find ways of controlling breast and other cancers.⁸ By the 1960s observational studies of screening by breast x-ray¹⁰⁻¹² and thermography^{22, 23} were being undertaken to investigate the potential value of these modalities as breast cancer screening tools. The technical difficulties of creating reproducible and reliable x-rays (increasingly known as mammograms) at an affordable cost and acceptable radiation dose were being successfully addressed.^{10, 13, 15, 24}

1.4 Screening by mammography - evidence of benefit from early trials

In the early 1960s, researchers at the National Cancer Institute (NCI) in the United States of America, a government cancer research and training organisation, were interested in

definitively studying the impact of early diagnosis by screening on breast cancer mortality.¹ A plan was developed to conduct a randomised controlled trial to explore this question. The initial proposal was for a study of screening by mammography using a slight modification of a standardised technique recently described by American radiologist Robert Egan. The protocol was later modified to include screening by physical examination, after recognising that while mammography was particularly good for screening large breasted women, in whom screening by physical examination could be unsuccessful, it might miss clinically palpable tumours in others.^{9,25} The trial was run through the New York health maintenance organisation, Health Insurance Plan (HIP), recruiting HIP patient volunteers and using HIP staff. It began in 1963, with 62,000 asymptomatic women aged 40-64 years. According to the trial's radiologist, Phillip Strax, (1967, reported by Kunkler^{26p249}) the lower age limit was chosen to avoid inadvertent radiation damage to an unborn fetus since "there were very few women who had children after that age." The intervention cohort was offered annual screening for four years and 65% attended at least one screening session; the control group received usual care, with no breast screening.^{1,16}

The HIP trial suggested promising results after just four years of data:²⁷ for women who were over 50 years of age at the time of the initial screen there were fewer breast cancer deaths in the intervention cohort than in the control group. The researchers advised that longer follow-up was needed to confirm whether or not the apparent mortality benefit was persistent but overall they expressed "cautious optimism"^{27p1785} about the future of breast screening. They perspicaciously suggested that efforts should be made to accelerate mammography capacity and capability, in order to cope with what might become a high public demand for breast screening.²⁷ The American response was immediately enthusiastic: in 1973 the NCI

collaborated with cancer advocacy organisation, the American Cancer Society (ACS), to fund a five year project offering annual breast screening by physical examination, mammography and thermography in multiple centres across the country, targeting women between 35-74 years. These 27 Breast Cancer Detection Demonstration Projects (BCDDP) were designed to demonstrate the feasibility of mass population breast cancer screening and publicise the benefits to lay and medical communities.¹ They were hugely popular with the public, despite awareness in the scientific community about the possible health dangers of radiation exposure from medical x-rays.^{1, 28-30} Concerns about the high radiation dosages and carcinogenic potential of mammography, particularly for younger women were raised at the onset of the BCDDP in the early 1970s, and within a few years women under 50 years of age were only allowed to participate if they were deemed to be at high risk of developing breast cancer. The interpretation of risk was variable, with some centres considering most women (i.e. up to 80%) under 50 years to be eligible for participation.¹

The international medical community continued to debate the usefulness of mammographic screening and sought to gather further evidence.³¹ While there was general support and widespread public advocacy for the concept of early diagnosis, some of the medical community were fully aware that apparent improvements in survival amongst patients diagnosed through cancer screening may well be due to lead time and/or length time bias (see **List of special terms and abbreviations**).^{28, 32} Others were apprehensive that screening by mammography or thermography may not add much, or anything, to the existing strategies of clinical and self-examination, and furthermore, could be problematic. The particular concerns were that: [1] mammography could potentially cause harm through radiation;^{33, 34} [2] mammography and thermography may be insufficiently specific, thus delivering harms

through false positives; and [3] thermography may be insufficiently sensitive, thus delivering harm through delayed presentation after a misleadingly reassuring false negative result.^{28, 35}

Many who were enthusiastic about mammographic screening were at least partly motivated by frustration at the persistently high breast cancer mortality and morbidity rates.³⁶ Breast cancer death in younger women was a particularly visible concern: although breast cancer mortality rises with age, there are few other diseases that kill younger women, and in high income countries such as Australia, breast cancer was (and remains) one of the leading causes of death in this cohort.^{5, 34, 37} The mainstay of treatment was radical mastectomy with or without radiotherapy, with significant side effects. Newer modalities such as chemotherapy and hormonal manipulation were being investigated and particularly championed by clinicians such as the American surgeon Bernard Fisher, who claimed their superiority in what he thought of as a systemic disease.² Fisher's breast cancer model was that many cancers spread throughout the body very early in the disease, long before clinical or radiological detection was possible. This implied that systemic therapy was needed alongside surgery, thus treating tiny metastases as well as the primary tumour.^{6, 38} However this was not the mainstream disease model for breast cancer and the value of systemic treatments was uncertain. As late as the 1980s, many thought the impact of chemotherapy on breast cancer was limited, with some claiming that they could do little more than palliate.^{39, 40} There was considerable interest in avoiding the morbidity of a radical mastectomy, and an eagerness to find breast cancers at a time when they were small and node-negative, and thus more amenable to the much less disabling "simple" mastectomy, which preserved underlying muscles.^{41, 42} It was hoped that mammographic screening might be useful in this regard.³⁴

In the wake of the promising early results from the HIP study, additional breast cancer screening studies were instigated throughout Europe during the 1970s to provide further evidence about mammographic screening.⁴³ Technical changes to reduce radiation doses and improve breast image quality were also explored. X-ray equipment that was specifically designed for the soft tissues of the breast became commercially available. These so-called “mammography units” contained several important differences from general x-ray units that were largely used to view bony tissues, including: different target metals in the x-ray tube, resulting in x-rays with properties more suitable to the soft tissues of the breast; built-in breast compression devices that improved image quality; and the introduction of new photographic and film technologies.¹⁰ In 1985, Swedish radiologist Lazlo Tabar and colleagues published a short but highly influential report of the early results from their “Two County” randomised controlled trial (RCT), also referred to as the Kopparberg and Ostergotland trials.⁴⁴ They concluded that offering breast screening by mammography alone (i.e. without clinical examination) could produce a 30% reduction in the population breast cancer mortality rate. Their data corresponded with results from the HIP trial and from recently reported observational case-control studies in the Netherlands^{45, 46} and Italy.^{7, 47} The possibility that the results might have been compromised by error⁴⁰ or by extreme length bias from the diagnosis of “biologically localised breast cancer”^{48p868} was acknowledged in the academic literature, but it was widely believed that any such errors or biases, if present, were insignificant.^{55, 61, 62} Most people were optimistic that, finally, population breast cancer mortality and morbidity could be significantly reduced. The next step was to work out the details of screening protocols that would suit local populations, health systems, and economies.⁴⁹

1.5 The introduction of organised breast cancer screening by mammography in Australia

At the time of the widely publicised Swedish RCT on the benefits of mammographic screening, breast cancer was a significant disease in Australia:

“Cancer of the breast is the most frequent cancer in Australian women. Over 5000 women develop it and nearly 2000 women die of it, each year. Approximately one in 16 women will develop breast cancer during her lifetime, and one in 24 women will die of it. It causes the loss of some 32,000 women-years of life annually, 14,000 of which would have been lived before the age of 70 years. As a cause of the loss of years of life before 70 years of age in women, it is exceeded only by congenital malformations and other perinatal conditions, traffic accidents, and coronary heart disease.”^{50p86}

The most promising avenue for reducing breast cancer deaths appeared to be the early detection of disease by mammographic screening. It was already clear from the trials that screening could have a beneficial effect on mortality, and towards the end of the 1980s, the addition of chemotherapy and hormonal agents to surgery for early breast cancer was finally looking like it might improve things even further.^{7, 39} The pressing issue in Australia was how to translate the new evidence on screening into actual benefit for Australian women, and how to do so in the most cost-effective manner possible.⁵¹

Breast cancer screening by mammography had been occurring sporadically in Australia since the 1960s. For example, between 1961-1963, Sydney radiologist Marjorie Dalgarno had carried out 1300 mammograms on asymptomatic women attending the gynaecological cancer detection clinic at the Rachel Forster Hospital. The purpose of the investigations had been to identify impalpable tumours as well as build up knowledge and skills in the diagnostic setting: improving understanding about the normal range of mammographic appearances and developing a standardised technique.¹⁴ In 1971, enthused by the HIP study, another Sydney-

based screening centre, Mediceck, began offering screening mammograms to “apparently well” women aged 25 years and over, referred by their doctors.^{52p287} Nearly 12,000 women were screened between 1971-1975. A diagnostic breast clinic at The Wesley Hospital in Brisbane opened in 1982, and alongside diagnostic work it provided mammographic screening for asymptomatic, high-risk women referred by their doctors.⁵³ There were pockets of vocal support for breast screening, notably a Working Group convened in 1984 by the Australian Commonwealth Government’s peak medical research funding body, the National Health and Medical Research Council (NHMRC). They advised that mammography was not only an accurate and safe method for early diagnosis of breast cancer, but that early diagnosis was effective in reducing breast cancer mortality.⁵⁴

Further developments in breast screening in Australia were precipitated by the 1985 publication of Tabar’s widely anticipated report on the Swedish Two County trial⁴⁴ and by the subsequent Forrest report in 1986 that proposed the introduction of screening mammography in Britain.^{55, 56} Dedicated mammography screening services were introduced in selected centres throughout Australia, funded by state governments and private investors.^{51,}
⁵⁷ They used varying operational parameters, with differences in factors such as: recommended screening interval; starting age; finishing age; number of mammography views per breast; and whether or not clinical examination was included. In 1987, the Commonwealth Government began investigating the feasibility and cost of a nation-wide mammography screening program by providing guidance and financial support for a research component at existing and new state based programs. This included the collection of cost and performance data and exploration of recruitment strategies at each centre.^{51, 56} A second Swedish trial reported favourable mortality benefit from breast screening⁵⁸ and there was

general medical and political support for the “opportunity to modify the fact that more than 2000 Australian women die from breast cancer each year”.^{59p76} Funding for a national screening program was announced in 1990.⁶⁰

The National Program for the Early Detection of Breast Cancer officially began in 1991, taking several years to become fully operational (and changing its name to BreastScreen Australia in 1996). National guidance was provided through the National Advisory Committee for the Early Detection of Breast Cancer, and a National Co-ordination Unit had responsibility for overall management and evaluation of the Program. Each state and territory had its own State Co-ordination Unit (SCU), to oversee the delivery and monitoring of local breast screening services across a network of screening units and associated assessment centres. The program offered biennial breast cancer screening by mammography to all women from the age of 40 years, with particular emphasis on recruiting women aged from 50 to 69 years.⁶⁰

Screening providers were funded by public money via a combination of state and federal government budgets, and all screening and follow-up services were free of charge for women. This lack of an economic barrier was specifically intended to provide all women with an equal opportunity to attend screening. It was recognised however, that an unregulated program of free breast screening might be problematic: it appeared that (opportunistic) cervical screening was being over-used by those with the least need for it, resulting in excessive financial costs and adverse health effects with little or no additional benefit. The new breast screening program therefore was organised with a defined screening interval, providing greater cost-efficiency and minimising harm.^{61, 63}

Another strategy to ensure equality of opportunity to attend screening was the use of mobile screening vans to provide screening services to women living in rural and remote areas. The new program also aimed to work towards equality of outcome (in the form of screening attendance rates) across different sub-groups defined by age, marital status, socio-economic status, language and ethnicity. An early national benchmark was that recruitment of Indigenous women and women from non-English speaking backgrounds should be at least 50% of the rate of the general population.⁶⁴ These aims were implemented by producing a variety of promotional materials that matched the cultural and linguistic needs of all eligible women, and by specifically monitoring the screening attendance of different population sub-groups.⁶⁰

The new program aimed to find a suitable balance between delivering the benefits and avoiding the harms of breast screening by implementing national policies on false negative and false positive rates. In any screening program, these two test outcomes affect the delivery of benefits and avoiding of harms respectively, but they affect each other in such a way that minimising the false negative rate (in order to deliver maximal benefits) can result in an excessive false positive rate (and considerable harm). The new breast screening program approached this issue directly, deciding to guide the benefit:harm ratio by allocating national performance targets for false positive and false negative rates. Screening units and individual radiologists involved in the screening program were regularly monitored for compliance, and educational strategies were put in place to remediate as required.^{60, 61}

Financial costs also had to be balanced against benefits and harms when making decisions about how and when to screen. Annual, two-view mammography was likely to identify more breast cancers in the population than biennial or triennial, single-view mammography, but also lead to greater radiation exposure for women, and result in higher financial costs. The final recommendation of biennial, two-view mammography was a compromise protocol.^{51, 61}

The selection of the screening age range also required decision-makers to balance a number of important public health concepts. On the one hand, screening appeared to be popular amongst women, including younger women, and as such there could be an argument that free access should be provided for women of all ages. On the other hand, the evidence about population mortality benefit for women under 50 years of age was limited, and likely to be lower than the benefit for older women because of the reduced breast cancer incidence in younger women. In addition, screening related harms (false positive and false negative results) would be more common in younger women due to the limitations of mammography for a pre-menopausal breast. Finally, because the benefit:harm ratio was lower for younger women than for older women, the program's financial cost-efficiency would be lower if screening were made available to young women. The final protocol gave free access to breast screening for all women over the age of 40 years, but particularly targeted and promoted screening to women aged between 50 and 69 years.^{51, 61}

Personal privacy was another issue for policy makers, and this came into conflict with their interest in delivering health benefits. In order to achieve the predicted breast cancer mortality reduction the program needed a high participation rate. Personalised letters of invitation and regular reminder letters were determined to be the most effective recruitment strategy, but

this required information to identify and contact the relevant population. Electoral rolls contained the relevant age, gender and contact data, but these records had been collected specifically for election purposes and there was some discomfort about using them for other reasons. The matter was largely resolved in favour of delivering benefits: utilising electoral information to send personal invitations, although breast screening units only had access to data about women in the target age range (50-69 years).⁶⁰

1.6 Breast screening: the last 25 years

Since the introduction of organised breast screening into Australia, there have been several additions to the evidence base for breast screening. During the 1990s the RCTs that had commenced in the wake of the HIP trial began delivering their results. None of them suggested the same level of benefit that the HIP and the Two County trials had reported, although most reported results with similar trends.⁶⁵⁻⁶⁷ The exception was a Canadian group, who reported that screening by mammography resulted in more diagnoses of breast cancer but no change in breast cancer mortality compared with physical examination for women between 50-59 years, and no perceptible breast cancer mortality reduction associated with combined mammographic and clinical breast screening for women aged 40-49 years.^{68, 69} The results of these studies did not reduce enthusiasm for screening by mammography: there was widespread criticism of the Canadian study methods^{70, 71} and much confidence that improved mammographic technology would deliver even more mortality benefit.

Researchers began to perform systematic reviews and meta-analyses on the breast screening RCTs, pooling study numbers with the aim of improving knowledge and reaching greater

certainty of results. Depending on which of the studies were included, a variety of claims about the impact of mammography screening on breast cancer mortality were made. For example, in 1993, a published review of the Swedish studies suggested there would be a 24% breast cancer mortality reduction in a population invited to mammography screening, with 29% in women aged 50-69 years.⁷² In 2000, a controversial Danish review of all the RCTs to date claimed that many of the studies should be excluded because of apparently inadequate methodological quality, and concluded there was “no reliable evidence that screening decreases breast cancer mortality”.^{73p133} The most recent review was published in 2013 by a group of independent experts who had never published on breast screening, in an effort to at least be seen to provide an “objective ... assessment of the evidence”.^{74p2208} This group calculated a population breast cancer mortality benefit of 20% amongst women invited to participate in mammography screening, although noted that “a great deal of uncertainty surrounds this estimate”.^{74p2207}

There has been even more controversy over the evidence relating specifically to the amount of breast screening mortality benefit for the cohort of women less than 50 years of age. The early RCT and observational trials had reported that the observed breast cancer mortality reduction associated with mammographic screening was only significant in women who were 50 years or older at the time of initial screen.^{27, 44-46} Various theories to explain this were put forward, including: [1] the possibility of a more rapid cancer growth pattern in younger women, meaning less opportunity for mammography to find asymptomatic cancer⁷⁵ (see **Appendix 2** on breast cancer pathology); [2] lower mammographic sensitivity in younger (pre-menopausal) women due to increased radiographic density; that is, the increased amount of hormone-sensitive glandular and stromal tissues radiographically obscures any

abnormalities⁴² (see **Appendix 3** on the breast screening process); and [3] smaller absolute numbers of cancers in younger women, meaning that trials were insufficiently powered to find any significant benefit (this latter argument generally included an explicit or implicit suggestion that a mortality benefit was, in fact, present).^{51, 54}

Differing responses to the evidence about younger women led to international variation in screening protocols. For example, the UK breast screening program was set up to only be accessible for women who had turned 50 years.⁵⁵ The Australian program targeted women from the age of 50 years, but allowed women from the age of 40 years to access screening upon request. Advice issued by government and non-government bodies in the USA has varied over the last 25 years; suggestions that screening might not be beneficial for women under 50 years have been met with enormous public outcry and political intervention (see **Chapter 3** for more detail on this). Despite recent updates to trial data, the evidence remains limited and the debate is ongoing.⁷⁶⁻⁷⁹ Many believe that any breast cancer mortality benefit will, at best, be small.⁸⁰

The previously mentioned Danish group who performed the highly controversial meta-analysis of breast screening trials went on to suggest that screening by mammography is not justifiable, because the harms are likely to outweigh the (limited) benefits.^{73, 81} This triggered renewed interest in the harms of screening, including false positives and overdiagnosis (see the **List of special terms and abbreviations**). An American group made the obvious, but previously little discussed, observation that some breast screening protocols and practices made it likely that a woman would experience at least one false positive in her lifetime.⁸² Other researchers began to study the topic of overdiagnosis in more depth. It had already

been realised that screening mammography resulted in a huge increase in diagnoses of in situ cancers, with incidence figures jumping by up to 500%.^{83, 84} Although the natural course of carcinoma in situ was unclear,⁸⁵ it was thought that more than two thirds would never become clinically significant,⁸⁶⁻⁸⁸ and therefore fit the definition of overdiagnosis (see **Appendix 2** for notes on breast cancer pathology). As it was unclear which would progress and which would not, most women with in situ cancers were – and still are - recommended to have surgical treatment, often mastectomy if widespread.⁸³ More recently, epidemiological evidence has begun to accumulate to suggest that some invasive cancers diagnosed through screening mammography are also indolent (destined to grow slowly, if at all) and therefore similarly falling into the category of overdiagnosis. Again, it is not possible to determine overdiagnosis in any individual breast cancer patient. Attempts to quantify the extent of overdiagnosis of invasive cancer have delivered huge variation in results, ranging from 0 to over 50% of cases. This wide variation is attributed to one or more of different methodologies, different screening parameters, and different populations.^{89, 90} **Chapter 2** contains more information on overdiagnosis. **Appendix 5** contains further detail on current controversies around interpretation of the evidence relating to breast screening.

Changing ideas about the benefits and harms of breast screening, together with an appreciation of improved treatment efficacy, have led to a recommendation from the Swiss Medical Board, an independent health technology review board, that breast screening be discontinued in their country.⁹¹ In other countries, those sceptical of breast screening efficacy have made more incremental changes, concentrating on ensuring that women are aware that the benefits and harms of breast screening may be closely balanced.^{92, 93} At the same time, mainstream medical opinion continues to remain enthusiastic about early

diagnosis by breast screening: increasing life expectancy has resulted in extensions to the upper age recommendations for mammographic screening, and more sensitive screening modalities such as MRI and tomography are being used and trialled respectively. It seems likely that there will be ongoing debate and discussion about breast screening for some time to come.

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Chapter 2: Social and ethical considerations in breast cancer screening

2.1 Chapter Introduction

This chapter provides background material on social issues relating to breast cancer screening. It also includes introductory material on relevant ethical issues, summarising and analysing the existing literature. Detail about how I searched the literature is provided in **Appendix 4**. In later chapters I will present my original empirical research about these ethical issues.

This chapter contains the following publication in press:

Parker L, Carter S. Social and ethical considerations in breast cancer screening. In: Houssami N, Miglioretti D, editors. Breast Cancer Screening: The Scientific Evidence. USA: Elsevier. In press 2016.

The manuscript and reference list are formatted as per the publishers' specifications, and hence do not correspond to the formatting in the rest of this thesis.

Abstract

In this chapter we discuss social and ethical dimensions of breast screening. Breast screening has influenced, and been influenced by: attitudes towards the breast and breast cancer; increasing emphasis on responsibility and risk in healthcare; and prevailing biomedical approaches to early detection of cancer, technological innovation, and evidence based medicine. Commercial and advocacy interests, and the political nature of breast screening have shaped its social character. Ethical considerations in breast screening include: maximising benefit (within resource constraints); minimising harm; delivering more benefits than harms; respecting autonomy; maintaining honesty, transparency, and just decision-making; respecting privacy; distributing benefits and burdens fairly; and valuing reciprocity and solidarity. We discuss these, and consider ethical challenges, including disputes over evidence of benefit and harm, and balancing conflicting ethical principles. Attending to social and ethical aspects of screening will assist policymakers and practitioners to proceed in a justifiable and legitimate way.

Introduction

In this chapter we consider the social and ethical dimensions of breast screening. Breast screening is grounded in science, but it is also part of society. Like any large scale public health program, breast screening exists in a two-way relationship with the society in which it is located, being subject to the values and conventions of that society,(1, 2) but also influencing future social attitudes, values and practices.(3) We will look at the many ways in which social structures and conventions, and moral and ethical thinking, interact with breast screening policies and practices. Our discussion is in two main sections. First we consider social aspects of breast screening: social attitudes and ideas that influence or are influenced by breast screening. Secondly we examine ethical aspects: considerations about right and wrong with regard to breast screening.

Social aspects of breast screening

Social norms and structures interact with breast screening in many ways. They may act as facilitators or barriers to the implementation of and public participation in breast screening, and may themselves be influenced by breast screening policies and practices. Below we discuss key aspects of the interactions between society and breast screening, focusing on those that have been most studied and discussed in academic and lay literature.

Social attitudes towards breasts and breast cancer

Breast screening is influenced by more general social norms and values regarding the breast itself. Because the breast is associated with sexuality and motherhood,(4) disease and treatment of this organ is highly emotive and associated with particular fear and anxiety.(5)

Women may feel embarrassed about breast disease, and hesitate to seek medical attention for breast symptoms. Breasts, particularly youthful looking breasts, are a popular topic for the media, raising the profile of breast cancer higher than might be expected from its medical impact alone and higher than for any other cancer.(6, 7) This media coverage is an important source of information for many women (8) but is also skewed towards reporting breast cancer in young and conventionally attractive women,(9) despite breast cancer incidence being much higher in older women.(8, 10)

Many authors have suggested that both breast screening , and public communication encouraging women to participate in screening, have changed the way that breast cancer is understood in society, and may also have changed the profile of the disease itself. Most authors agree that the introduction of screening has coincided with a sharp and sustained increase in breast cancer incidence and prevalence. The rise in incidence may be at least partly due to overdiagnosis.(10, 11) Similarly the rise in prevalence may be inflated by a combination of increased lead time and improved survival as a result of screening, along with contemporaneous improvements in treatment.(12-14) The impact of this increase on the number of breast cancer patients and survivors has been discussed by many writers, some of whom hold potentially conflicting views. It is suggested that breast screening may have:

1. reduced embarrassment and nihilism about symptomatic disease, thus facilitating earlier presentation;(15)
2. artificially inflated fear of breast cancer death;(16, 17)
3. artificially inflated belief in breast screening benefits;(16, 18) and
4. made women vulnerable to overmedicalisation, leading them to demand screening and precautionary treatment even when it is unlikely to be beneficial.(19)

Some authors are particularly critical of the use of fear in breast cancer or breast screening communication. They point to the media presentation of breast cancer as a mysterious, increasing, frightening ‘epidemic’, predominantly striking premenopausal white women in their prime years. These authors point to the inaccuracy of this depiction, and some suggest it has been deliberately engineered as a tool to encourage participation in screening.(9, 10, 20, 21)

Summary: social attitudes towards breasts and breast cancer

- The symbolism of the breast (motherhood and sexuality) means breast cancer is highly emotive and breast screening is a popular media story, potentially contributing towards attitudes towards breast screening.
- Screening may affect social attitudes about breast cancer via its contribution towards increasing public familiarity with the disease.

Sociology of health and illness

Breast screening resonated with general cultural and social trends in the second half of the 20th Century relating to health risks and responsibilities. Many authors note an increasing expectation, beginning in the 1970s and 80s, that individuals could, and indeed, should, make ‘lifestyle choices’ to improve their health.(6, 9, 21) These authors suggest the introduction of breast screening has contributed to a ‘personal responsibility’ model of breast cancer, by providing an opportunity for women to take individual responsibility for breast health.(6, 22) There are two concerns with this model: firstly, the opportunity to participate in breast screening may have become a social obligation, with normative repercussions and judgement

against those who do not screen, especially if they develop breast cancer.(6, 22, 23)

Secondly, there is concern that preoccupation with screening may have deflected attention from studying other methods of breast cancer control, such as primary prevention.(6, 9, 24, 25)

Other writers have noted an increasing tendency to subject ourselves to medical attention,(26) including widespread general enthusiasm for testing and screening.(27) Relatedly, sociologists have extensively documented the increasing risk awareness and risk aversiveness that characterises contemporary society. This seems especially pertinent here, as women have been shown to be particularly aware of themselves as being at-risk for breast cancer as opposed to other conditions,(28) and to overestimate both their risk of dying from breast cancer and the protective benefit of mammography.(16, 18)

Summary: sociology of health and illness

- Breast screening fits with the increasing tendencies of society to place responsibility for health upon individuals, and to be aware of and averse to risk, particularly high profile risks such as the risk of dying from breast cancer.

Biomedical culture

Breast screening has arisen in the context of prevailing biomedical paradigms regarding cancer growth and control, the use of technology, and evidence-based medicine (EBM).

Breast screening, as an important practice in preventive health and medicine, has arguably contributed to these paradigms. We discuss each of them below.

The first example of the relationship between breast screening and biomedical paradigms relates to the conceptualisation of breast cancer as a disease. For decades breast cancer has been predominantly understood as having a linear growth pattern, progressing from a localised focus of abnormal cells or in situ cancer, to invasive and potentially metastatic cancer.(5, 29) This helps to explain the inherent acceptability of breast screening as a policy. The most successful methods of control for women without specific genetic abnormalities have been assumed to be early detection and intervention and this has contributed greatly to the widespread support for breast cancer screening amongst the medical profession. Although this paradigm is still dominant, some writers are challenging its hegemony, suggesting that some breast cancers may regress (30) or adhere to non-linear growth patterns.(31) It remains to be seen whether these or other theories become more widely accepted and influence the future of breast screening.

Breast screening is seen by some writers as an example of the technological imperative in action; that is, some propose that screening was adopted in part because both women and experts believed in the technology itself.(32) The implication here is that belief in the technology may have been at least as significant a factor in the popularity of breast screening as evidence of benefit.(33) This is particularly discussed in relation to the encouragement of women under 50 to participate in breast screening, despite lack of evidence about benefit for this age group in early randomised controlled trials (RCTs).(9, 29, 34) More recent developments in breast screening suggest that the technological imperative may be losing force as we learn from past experience: newer screening modalities that appear to offer increased test sensitivity are being approached with some caution and concern regarding overdiagnosis.(35)

The rise of EBM has paralleled the production of evidence about breast screening. Breast screening proved to be highly conducive to epidemiological study, and the large amount of RCT and other evidence generated around this topic was an important reason for its broad acceptance by the biomedical community. In turn, it may be speculated that the perceived success of (evidence-based) mammographic screening programs gave a boost to the EBM approach.

Summary: biomedical culture

- Breast screening has arisen within the context of, and has contributed towards, the culture of biomedicine.
- Breast screening has supported and been supported by approaches to the early detection of cancer, technological innovation, and EBM.

Commercial and institutional aspects of breast screening

Breast screening has become heavily institutionalised in Western society and culture. Many writers express concern about commercial interests in this process. They point to a range of actors including pharmaceutical companies, equipment manufacturers, professional medical organisations, and corporate donors who are doubtless motivated strongly by the desire to prevent women from dying of breast cancer, but have additional commercial interests.(9, 24, 36)

Breast cancer advocacy is one notable institution related to breast screening. Breast cancer advocacy groups are large, powerful and highly visible social institutions with recognisable

symbols (pink ribbons) and traditions, such as the Komen Foundation Race for the Cure.(15)

The high profile of breast cancer advocacy means that breast cancer consumer voices are taken seriously as a legitimate form of public opinion and power. Many breast cancer advocacy groups believe strongly in early detection by screening (37) and campaign for screening resources and services.(6) Some authors suggest that the symbolic significance of the breast previously discussed makes it easier to raise funds for breast cancer causes (including breast screening) than for some other conditions,(9, 24) helping to explain the relatively strong funding base and profile for breast cancer advocacy.

Summary: commercial and institutional aspects

- Key stakeholders may have commercial interests that influence their participation in breast screening.
- Breast cancer advocacy is powerful and bolsters support for breast screening.

The political nature of breast screening

Many authors have ascribed the political popularity of breast screening partly to its easily quantifiable outcomes, which can be readily presented as success stories, but more importantly to its role as a ‘women’s issue’ that will attract votes.(25, 38, 39) Breast screening is seen as a ‘safe and non-controversial’ women’s issue, unlike, for example, abortion or domestic violence. This is illustrated by the willingness of women in political life to be candid about their breast cancer experiences (think here of Betty Ford or Happy Rockefeller).(32) By contrast, when Janette Howard, wife of the then Prime Minister of Australia, was diagnosed with cervical cancer her disease was not made public.(40)

The lively advocacy environment surrounding breast screening also illustrates its political nature (7, 9, 19, 32, 38) and contributes to the frequent politicisation of breast screening. For example, when the 1997 Consensus Conference by the US National Institutes of Health (NIH) removed its endorsement of routine screening for women aged 40-49 years, suggesting instead that it be a personal decision, many advocates organised against the change. Their political influence was strong enough to encourage the US Senate to pass a resolution urging the NIH to reconsider, and ultimately the NIH re-endorsed routine, annual mammography for this age group.(25) Twelve years later, breast screening again returned to the centre of political attention. In 2009 the United States Preventive Services Task Force (USPSTF) also recommended that screening for younger women (aged 40-49) be an individual choice rather than standard practice, provoking immediate and intense condemnation by advocacy and clinical leaders. The US Department of Health and Human Services quickly issued a statement to distance itself from the recommendations, stating that federal breast screening policy would remain unchanged and assuming that private health insurers would follow their lead. The US federal health insurance program *Medicare* continues to provide coverage for annual breast screening from age 40.(41, 42)

Summary: politics

- Breast screening tends to be both politically popular and politically contested, which influences the design of policy and practice.

Ethical issues in breast screening

Public health, economic, and perhaps legal criteria are commonly cited as guidelines for planning or evaluating screening programs.(43, 44) Explicit inclusion of ethical or moral criteria is less common. Although many of these evaluative criteria include implicit ethical principles (such as: maximising benefits; minimising harms; and, more recently, respect for autonomy, voiced as requirement for informed consent), a formal ethical approach can provide additional value. First, it can provide depth of analysis, making arguments for why principles are important and should be upheld. Second, it draws our attention to additional considerations that have not traditionally appeared in screening ethics frameworks. For example, ethicists focused on screening have not only written about why it might be important to obtain informed consent for screening,(45-47) but also about the tensions between promoting individual health, promoting community health, and respecting autonomy.(48) They have also considered the ethical implications of professional, institutional, and consumer tendencies to start and, once started, to continue preventive screening programs and to under-recognise the potential for this screening to do more harm than good.(47, 49)

The ethics of screening are made more complicated by its location on the boundary between clinical and public health practice. Although some of the ethical issues faced by clinical medicine versus public health are similar, others are quite different. Many readers will be familiar with the Beauchamp-Childress principles for clinical ethics (respect autonomy, do good, avoid harm, seek justice); in recent years authors have proposed alternative sets of principles for public health ethics.(50-54) We will consider both clinical and public health principles, beginning with those that are more frequently discussed and debated within breast

screening. Note that some of these principles are more contentious, and so require more space to discuss. This is not meant to imply any greater importance, but might suggest these issues are deserving of more extensive societal debate.

The public health ethics and screening ethics literatures (45, 51-54) suggest the importance of these ethical issues when evaluating breast screening (46-50):

- Maximise health benefits
- Minimise harms
- Deliver more benefits than harms
- Deliver the most benefit possible within the resources available
- Respect autonomy
- Maintain transparency, including communicating honestly
- Distribute benefits and burdens justly
- Uphold reciprocal obligations
- Act in solidarity with others

We will consider each of these in turn.

Maximising health benefits through breast screening

The goal of improving the health of populations is central to public health practice. There has been considerable debate over the degree to which public health policies should deliberately contribute to individual and societal well-being beyond health, an issue we will consider later in this chapter. In this section we concentrate specifically on health benefits. In

general, a program that delivers greater health benefit can be considered more justifiable, primarily because—in many ethical traditions—good consequences have moral value in themselves. In addition, delivering these benefits keeps the promises that have been implicitly or explicitly made about the program.

Public health is generally characterised as being concerned with health benefits in *populations* rather than primarily focussing on *individuals*.⁽⁵⁵⁾ In population breast screening, for example, a public health perspective would predominantly focus on the degree to which screening increases the longevity and quality of life of women on average across a population, rather than being concerned with benefit delivered to individual women. It is useful to consider the distinction between benefits to populations and benefits to individuals since it is less clear than it may seem, especially for an activity like screening. This is in part because benefits to populations are of more than one type. They include all of the benefits experienced by individuals added up (*aggregate benefits*) but many public health programs also provide additional benefits, sometimes called *corporate benefits*, that occurs at the population level only.⁽⁵⁶⁾ For example, vaccination programs deliver aggregate benefits (all of the instances of personal protection via immunisation, added up) but also corporate benefits (the herd immunity that arises only after a certain proportion of the population is vaccinated, and which protects even those who are not vaccinated). The various aggregate and corporate benefits of breast screening are discussed below.

Breast cancer mortality benefits

Breast cancer screening delivers breast cancer mortality benefit for some age groups.⁽⁵⁷⁾ The introduction of breast cancer screening into a population has been shown to result in a

reduced population breast cancer mortality rate. This is mainly because some women who are screened derive benefit from their participation (the sum of which provides an aggregate benefit), although the existence of breast screening may also provide corporate benefits to women in general (discussed later in this chapter).

For some public health programs, aggregative population benefit is widely and equally distributed amongst most people. For example, in vaccination programs where most children participate, the benefit is approximately the same for each child. Not so for the breast cancer mortality benefit of screening: most women who attend breast screening receive no breast cancer mortality benefit at all, and attending screening will not make any difference to whether or not they die of breast cancer. This is because most women, screened and unscreened, will not develop breast cancer. Of those women, screened and unscreened, who do develop breast cancer, many will not die from it if they undergo current treatment regimes. Still others, sadly, will die from it regardless of whether or not they attended screening. It has been calculated that less than one in seven women who are screen-diagnosed and treated for breast cancer receive mortality benefit from their screening.(58) Thus the aggregate disease-specific benefits of screening clearly exist, but are unequally distributed in the population, being derived from a small number of women.

This aggregate benefit, derived from a small number of women, remains the dominant driving force behind mammography screening. Recent attempts to quantify breast cancer mortality benefit suggest that screening is less beneficial than was calculated in most of the early RCTs, partly because of revised calculations from the original studies,(57, 59) and partly because of recent improvements in treatment, which reduces the margin for benefit

from interventions such as screening.(14) Writers also express concern that breast cancer screening has very little impact on *all-cause* mortality.(60)

The likelihood of deriving breast cancer mortality benefit from screening may vary between women and between populations of women. Individual women at increased risk of dying from breast cancer will be more likely to derive benefit from screening, and conversely those at decreased risk will be less likely to derive benefit. The latter group includes young women, (since they are much less likely to get breast cancer than older women) and women who are more likely to die from other causes (e.g. due to age or significant co-morbidities). Similarly, populations of women with a higher incidence of breast cancer will derive more absolute mortality benefit from screening, and populations with a lower incidence (e.g. communities in many parts of Asia (61)) will derive less benefit. This raises questions regarding screening policy, and the extent to which programs should consider themselves obliged to focus screening on those sub-populations of women which are most likely to experience an (aggregate) mortality benefit. Thus far, within a given population, outside of age and (uncommon) genetic markers, most risk factors for breast cancer are modest and thus of limited use in stratifying screening.(62) Recent research on risk factors such as family history of breast cancer in first-degree relatives, and personal breast density may alter this. Women in their 40s at high risk of breast cancer may have similar benefits and harms from breast screening as average risk women aged 50-74, and thus might consider screening at an earlier age.(63-65)

Breast cancer morbidity benefits

Breast cancers identified through screening programs tend to be smaller and more amenable to breast conserving treatment than cancers that present symptomatically. This is often mentioned as a benefit of breast screening programs but is controversial. If the breast cancer detected was destined to progress and become more difficult to treat, then the woman concerned has certainly experienced a morbidity benefit. However some researchers are concerned that many small, asymptomatic cancers identified through breast screening are indolent – cancers that would never otherwise have come to the attention of the woman.(11, 66) If this is so, breast-conserving treatment cannot be counted as a benefit, since no treatment was necessary. This problem of unnecessary diagnosis and management of non-progressive cancers produces the overdiagnosis in breast screening programs; there is little consensus on how common it is. Overdiagnosis is discussed in more detail later in this chapter. In addition, several writers have expressed concern that screening has led to an increase, rather than a decrease, in mastectomy rates. This may be due to the ability of screening to detect certain abnormalities in the breast that have an uncertain prognosis, but are widely spread throughout the breast and unsuitable for local surgical treatment (lumpectomy).(11, 67) This remains controversial.(68)

Psychological benefits

Since the majority of women are not destined to develop breast cancer, most women will receive a negative screen. While some argue that the reassurance of a negative screen can justifiably be counted as a benefit of screening, others disagree. Those who object give several reasons, including that in some cases the screening result will be wrong (a false negative), so screening may sometimes deliver false reassurance.(11) More generally,

though, since it has been consistently shown that both the fear of breast cancer death and the expectation of mortality benefit from screening are inflated relative to what the evidence would support,(16, 69) it is argued that a woman's *subjectively experienced* reassurance from a negative screen may be considerably inflated relative to our best estimates of her *objective risk* of developing breast cancer. This distorted perception of risk may have at least in part arisen from the communication campaigns of public health communication about breast screening.(11) If this is true, without denying women's subjective experience of reassurance, including it as a benefit of screening is questionable. In addition, a wrong may be done to women if they are implicitly or explicitly misled about the degree to which they are at risk and the degree to which participating in screening may prevent their death.

Does breast screening offer corporate benefits?

Many people consider that a population's benefits for cancer screening are accrued only as aggregate benefits: the sum of benefits experienced by (a few) individuals as a result of participating in screening. Others describe several corporate benefits, added benefits that accrue to an entire community as a result of breast screening policies and practices. First, screening promotion campaigns have arguably improved public awareness and knowledge about breast cancer and, as noted above, this familiarity with disease may facilitate earlier presentation amongst women with symptomatic breast disease.(70) Second, operating a breast screening program within a population may generate a sense that society cares about women, and is willing to support them and provide them with services. (This is considered in more detail below.) Finally, although it is impossible to assert a causal link, the introduction of breast screening is widely considered to have catalysed better breast cancer management, facilitating an improvement in the co-ordination and operation of breast cancer treatment

through better experience, training and monitoring of medical specialists, and the introduction of multi-disciplinary team care.(71) This has meant better outcomes and experiences for all women with breast cancer. Note, however, that these latter benefits have, to a large extent, already been delivered and are likely to continue, whatever happens to screening. Thus they seem relevant for an evaluation of past screening programs, but arguably are not relevant to our assessment of how screening should occur in future. This is in contrast, for example, to herd immunity, the corporate benefit of vaccination programs, which depends entirely on their continuing operation.

Summary: benefits

- Breast screening delivers breast cancer specific mortality benefits and may deliver all-cause mortality benefits.
- Breast screening may deliver morbidity benefits (less aggressive treatments but possibly some unnecessary treatments).
- Consumer reassurance may or may not be a legitimate benefit for many women who participate in screening.
- Introduction of breast screening has stimulated additional, population-wide benefits (e.g. improved management) but this may not be a pertinent justification for future screening programs.

Avoiding or minimising harms

Evaluations of public health programs often focus on delivery of benefits. However any intervention on an individual or population can also do harm. In clinical medicine, this

concept is covered by the principle of non-maleficence: avoiding doing harm associated with patient investigation or treatment. While non-maleficence is an ancient and widely-recognised principle of clinical medicine, the idea that public health policies such as screening can do harm is less-well recognised.(47) It may not be possible to completely avoid harms in public health programs, but in general a more ethically justifiable program is thought to be one that minimises harms for participants and populations.

Many of the harms discussed below are relevant to any screening program, but here we focus on the relevance to breast screening.

Inconveniences and financial costs of participation

It is well recognised that participation in breast screening incurs inconveniences and difficulties such as taking time away from work or child care to attend appointments, psychological anxiety, and pain.(72) Although these are generally perceived as being relatively inconsequential, they are persistently cited by consumers as notable aspects of the breast screening experience and policy makers should continue to work towards addressing such concerns. In many countries, a screening mammogram and any associated investigations also incurs financial costs.(73)

Harms related to the test

Radiation harms associated with modern mammographic screening are widely recognised to be acceptably low for women 40 and older.(74) The radiation dose is higher for women who have dense breasts and for women with very large breasts, thus radiation exposure may be

more problematic for pre-menopausal women and large-breasted women, particularly if having frequent (e.g. annual) mammographic screening.(75) Greater radiation exposure associated with adding newer tomography screening modalities is currently of concern, and research is continuing to address this.(76)

Harms related to test results

Harms associated with test results include technical faults and false positive results requiring recall and repeat testing, and false negative results. Recall for technical faults or false positive screens deliver physical harms of additional mammograms and possibly fine needle or core biopsies. In addition to physical harm, these also carry risks of psychological harm and, in many countries, extra financial costs.(73) It has been estimated that the psychological distress associated with false positive mammography can last for over three years.(77) The likelihood of a woman receiving a false positive diagnosis during a lifetime of screening varies greatly with the location and parameters of the screening program. It also accumulates such that a regularly-screened woman's risk of having a false positive in her lifetime is much higher than her risk of having a false positive as a result of a single test.(78-81) False negative results are much less common but may also cause harm through false reassurance and delayed presentation of symptomatic disease.(82)

Harms arising from the limitations of screening

Overdiagnosis and over-detection of invasive and in situ cancers are also harms of breast screening. At present indolent cancers cannot be distinguished from progressive, potentially lethal cancers, so once breast cancer is detected, almost all women are treated. Treatment is

generally unpleasant and may be financially burdensome for the individual (for example, in the United States, even those with health insurance suffer considerable “financial toxicity” after a cancer diagnosis due to the rising costs of patient co-payments for cancer treatment (83)). Very occasionally treatment will result in patient death. Thus, at a population level, breast screening may be associated with unnecessary morbidity and mortality due to overdiagnosis. Despite intensive research there is currently no firm consensus on rates of overdiagnosis within breast screening.(66, 84, 85)

Breast screening does not always deliver certainty about breast health: sometimes screening uncovers lesions in the breast that are unlikely to progress to become cancers themselves, but may indicate a generalised increase in the likelihood of breast cancer elsewhere in either breast. This type of result might be seen as a harm because it produces heightened anxiety about breast cancer, but may not deliver an expected level of certainty about risk to the individual and may require substantial removal of non-cancerous breast tissue (e.g. single or double mastectomy) to reduce the woman’s risk and anxiety levels to those of an age-matched cohort without identified breast disease.(86)

Are harms justifiable?

There are several important points to consider when evaluating whether or not the harms associated with breast screening are justifiable. These include the size of the harm and how this should be measured, the extent to which harms can be predicted, whether it is possible to minimise harms and if so what other consequences may follow, and finally whether action should be taken to minimise harms. We consider each of these points below.

How much harm?

It has proven difficult to gain consensus on the amount of harm associated with breast screening. As noted above, despite many years of operation and many studies and meta-analyses, there remains substantial variation in calculations of cumulative false positive and overdiagnosis rates. At least some of the variation may be real: it may be that different screening protocols and different populations produce different amounts of population harm. Some of the variation may be methodological: differences in overdiagnosis calculations may contribute to the considerable disparity between estimates.(84, 85, 87) Writers have urged breast screening experts to reach consensus about how to measure overdiagnosis in order to make progress on this controversial topic.(88)

Anticipating harms

Some harms, particularly false positives and false negatives, are well anticipated prior to the implementation of organised screening, and programs only go ahead if and when it is possible to minimise these harms. Other harms are less well anticipated. For example, the possible harms associated with ionising radiation were unknown when mammographic screening was initially introduced sporadically in the 1950s and then widely implemented through several states in the USA in the 1960s and 1970s in the Breast Cancer Detection and Demonstration Projects.(32) (Since that time, mammography units have much improved and radiation doses considerably reduced.) Similarly, while overdiagnosis was occasionally discussed prior to widespread breast screening,(89, 90) it was generally assumed this would not be a significant problem. In particular, overdiagnosis of DCIS was not seriously considered since DCIS is usually impalpable (asymptomatic) and it was a rare diagnosis prior to the onset of screening. Recently there have been calls for researchers to make a more

deliberate effort to anticipate, investigate and report on possible harms associated with proposed (and existing) screening programs, (91) particularly in relation to the diagnosis of inconsequential disease.(44)

Minimising harms

When harms are anticipated (or should reasonably be able to be anticipated), ethical obligations to avoid harm imply that programs should be designed to not only maximise benefits, but also to minimise harms. In the context of breast screening, this includes close attention to quality control, and requires careful and ongoing monitoring of screening program procedures, parameters, and outcomes in order to identify and correct technical and procedural problems.(92) Program policies should incorporate activities before and after the testing stage, with identifiable standards and quality checks for all steps including recruitment and communication, repeat testing, and follow up. There is some concern that private opportunistic screening providers may not engage with the same quality control standards and parameters that public, nationally organised providers adhere to.(80, 93)

Notwithstanding these needs for quality control, the nature of screening means that harms cannot be avoided: minimising harms from false positive tests is likely to increase harms from false negative tests and vice versa. Program operators must decide how to balance their programs such that the various harms are best minimised.

Summary: harms

- Breast screening delivers harms to the participating population.
- There is no consensus on how much harm is delivered by breast screening.

- Close attention to quality control is required to minimise harms.

Delivering more benefits than harms

We have shown above that there are potentially both positive and negative consequences of breast screening: benefits and harms. For most people, having benefits outweigh harms is a necessary criterion for an ethically justified public health program. (We would add: necessary *but not sufficient*. That is, other morally relevant factors such as autonomy, transparency, and distributive justice should also be considered, and we discuss these and other principles below.) The process of weighing up benefits against harms is multi-layered. It includes, in no particular order: quantitative measurements of benefits and harms (which is controversial in breast screening, as discussed above); comparisons between qualitatively different benefits and harms; and the relative weightings ascribed to maximising benefits and minimising harms.

Comparing qualitatively different benefits and harms

Benefits and harms may be disparate in nature, making meaningful comparisons difficult. How, for example, should we compare population breast cancer mortality reductions against (possible) population breast cancer morbidity increases? The logic underpinning endorsed public health activities is that they should result in population health benefits that are clearly more substantial than the harms, and this has generally been the case with breast screening. For example, when organised breast cancer screening was introduced in Australia, the benefits from reducing breast cancer deaths was widely accepted to considerably outweigh the harms associated with occasional false positive or false negative tests. Since that time, as

discussed above, estimates of screening benefit have decreased and anticipated harms have increased, and it is now frequently suggested that the benefits and harms accruing from breast screening are closely balanced.(70, 94) In such a scenario, qualitative differences between screening outcomes make comparisons particularly troublesome. Translating screening outcomes into comparable units may have some similarities with the somewhat controversial use of QALYs (Quality Adjusted Life Years) for comparing disease outcomes. It is not clear who might be best placed to make such translations.

Should we prioritise maximising benefits or minimising harms?

The relative importance ascribed to maximising benefits and minimising harms may vary according to context and individual preferences.(95) In some circumstances, or for some people, avoiding harm may be considered a prioritised principle, that can rarely be traded off against benefit or any other principle. Again, where the differences between benefits and harms are clearly great, personal preferences about the importance of each principle may not significantly affect the outcome of balancing benefits against harms in population-level policymaking. For breast screening, where benefits and harms appear more closely balanced, individual differences in prioritising each principle may become more important.

Who should decide whether benefits outweigh harms?

Many writers think it important to involve citizens in such calculations. Citizens can be involved at policy level and at a personal participation level. Firstly, deliberative democracy methods such as citizens' juries can be used to determine public perspectives on comparing qualitatively different benefits and harms, and on the weightings that should be ascribed to

maximising benefits and minimising harms.(96) The rationale here is that lay people may value and trade off the various possible benefits and harms differently to policy makers and healthcare professionals. Secondly, many people suggest that individuals who are considering participating in breast screening can and should be more involved in deciding whether or not benefits outweigh harms in their particular case, because they are best placed to know their own attitudes towards these benefits and harms.(97) Consumer decision making is valued here for its usefulness as being the best way of deciding between somewhat similar or incomparable outcomes, independent of the intrinsic value of being able to make decisions for oneself (see more on this in the next section on respect for autonomy). This reasoning contributes to new breast screening communications with consumers that seek to present both benefits and harms and encourage informed choices about screening participation.(98)

Note, however, that obtaining informed consent does not remove responsibility from providers to minimise harms,(46) and breast screening policy makers arguably have a duty to deliver screening policies that the majority of the target population will accept. Many consider that benefits of screening remain substantial enough to outweigh harms and so breast screening should continue unchanged. Others disagree, and, notwithstanding the use of deliberative democratic methods to help ascertain public opinion, many writers are suggesting that breast screening programs should be more tailored to individual risk profiles in order to facilitate a more favourable balance of benefits and harms. For example: those at higher risk of dying from breast cancer, for whom benefits of screening are likely to be greater, should have more screening than those who are at lower risk of dying from breast cancer and are therefore less likely to benefit from screening.

Summary: delivering more benefits than harms

- Benefits and harms in breast screening are more closely balanced than previously thought.
- Given the qualitative differences between benefits and harms, and variations in how much to prioritise the principles of maximising benefits and minimising harms, it is hard to know where, exactly, the balance between breast screening benefits and harms lies.
- Involving citizens at the levels of policy making and individual decision making may assist with making this calculation.

Delivering the most benefit possible within the resources available

Given that resources for healthcare are always finite, resource allocation and the amount of benefit received for a given investment is worthy of ethical consideration. In the context of breast screening it is relevant to not only explore how much benefit can be delivered while minimising harms, but also how to maximise the benefits that matter *within a healthcare budget*.

Population breast screening is an expensive program, even when taking into account healthcare savings associated with earlier diagnosis and treatment, and containment of costs that might otherwise accrue from unregulated, opportunistic screening.(99, 100) The high cost of breast screening programs doesn't mean they shouldn't be funded, but it does mean there are opportunity costs to other potential areas of expenditure, and it may be useful to consider how breast screening costs compare with other healthcare expenses. There is

controversy over this,(101-103) partly due to lack of consensus over mortality benefit and overdiagnosis figures. It is also important to consider ways to keep breast screening as cost-efficient as possible. Attaining and maintaining a high level of public participation is often suggested as being necessary for the purposes of cost-efficiency (93) but this is contestable. For many screening programs, the main expenses are the variable (participant related) costs associated with actually performing the screens and follow up tests, rather than the fixed (set-up and infra-structure) costs, and as such, screening can be cost-effective even with low rates of participation.(104, 105) Given this, the common link made from cost-effectiveness to participation rates may be less certain than is sometimes suggested.

Summary: the most benefits within resources

- Cost-effectiveness of breast screening compared to other healthcare expenditure is controversial.
- For cancer screening generally, it is not clear that high participation rates are required to achieve cost effectiveness.

Respecting and Supporting Autonomy

Respecting, or supporting, the autonomy of individual patients, consumers, or citizens is a fundamental principle in healthcare ethics. For the purposes of this discussion, we regard an autonomous person as one who: sees herself as in being charge of her own life; believes this to be appropriate; and has the freedom, opportunity, skills and capacities required to make choices, take action, and live in a manner that is consistent with her sense of who she is.(106) Being autonomous thus relies not just on the person herself, but also the people, systems and

society that surround her. These relationships and systems can either support or diminish her autonomy.

Informed decision making in breast screening

The facilitation of informed decision making in breast screening is an important part of supporting and respecting autonomy. Many writers have expressed concern that breast screening communication with consumers should: 1) include evidence-based information about risks and benefits; and 2) be designed to inform women in a balanced way rather than persuade them to participate.(107, 108) Many countries have recently released or will shortly release new information pamphlets.(93, 98) We mentioned above that facilitating informed decision making about breast screening may be more likely to produce beneficial outcomes. This may be for several reasons, including: the experience of having one's autonomy supported may increase one's sense of wellbeing; also, if we believe that we are all best able to know our own interests, the choices we make for ourselves may be more likely to be beneficial to us. In this section, however, we present autonomy as something to be valued in its own right irrespective of the resulting consequences, and suggest that facilitating informed choice has independent value from whether or not it improves the benefit to harm ratio.(109)

How else should we support and respect women's autonomy in breast screening?

Providing opportunities for informed decision making is only one part of supporting and respecting autonomy. Other aspects of respecting and supporting autonomy in the breast screening context include:

- Communication that indicates women have the authority to decide whether or not participation is right for them (rather than suggesting that they should not question participation, or are in no position to decide);
- Ensuring that women understand the implications of participating or not participating in screening; and
- Ensuring that women have an opportunity to consider screening in the context of their own values and sense of self.(110)

How important is supporting and respecting autonomy?

Respecting autonomy is considered a very important principle in healthcare ethics. In the Four Principles approach within clinical ethics discussed earlier, respect for autonomy has been referred to as the ‘first among equals’.(111) Writers on public health ethics have recently tended to criticise excessive importing of clinical ethics concerns, particularly respect for autonomy, into public health contexts, arguing that this potentially overrides community-orientated principles such as justice, solidarity and reciprocity which are fundamental to public health practice. Certainly the extensive evidence that individual health is heavily influenced by social, as well as personal, factors suggests that it may be misguided to conceptualise respect for autonomy as being merely about independence of choice, or to prioritise choice above all other considerations.(112)

The principle of respecting autonomy may conflict with other principles discussed here. For example, it may be very hard to engage large numbers of women in informed shared decision making for a complex topic like breast screening, especially if they are not well-informed to begin with.(16) Some writers argue that enabling all consumers to make their own, fully

informed, choices about screening would be so resource-intensive and challenging that it would seriously undermine the cost-effectiveness of screening.(48) Others disagree, arguing that informing women about breast screening is not especially difficult (97) or that respecting autonomy should be such a high priority that we may be obliged to offer such information and support if breast screening is to continue, regardless of cost. Respecting autonomy may also influence the level of benefit delivered by screening. There has been concern that embarking upon an informed consent process for breast screening may worry consumers, and reduce public participation in breast screening programs, therefore decreasing the number of women who can benefit.(113, 114) Despite this, varied stakeholders support the principle of respecting autonomy strongly enough that there is reasonably widespread international support for shared decision making and informed choice in cancer screening.(113-115)

Summary: respecting or supporting autonomy

- Facilitating informed choice is an important aspect of respecting autonomy in breast screening.
- There is disagreement over whether or not facilitating informed choice might be excessively expensive or decrease public participation rates, and over how to balance support and respect for autonomy against other ethical principles.

Honesty, transparency and procedural justice

Ethically justified and legitimate public health decisions and actions will generally have the qualities of honesty, integrity and openness.(52,55) This is relevant to the substance of communication, and the process of decision making and implementation.

Ethically justified programs will pursue full and honest disclosure of information that might be considered relevant for consumer decision making. Communicating honestly is, in part, a way to show respect for individuals and their autonomy as discussed above, but many would also regard it as being important in its own right. That is, many think that governments should, as a general rule, be open and up-front when communicating about their policies and programs. Transparency in the full and honest disclosure of how, and by whom, decisions and policies are made is also important. This includes the disclosure of possible vested interests amongst policy makers and advisors in order to facilitate accountability and take account of possible bias.(52) Procedural justice is about fairness in decision making: for example, ensuring that all relevant stakeholders are included, that decisions are made for good reasons, that decisions are open to revision if new evidence or arguments emerge, and that the influence of biases and vested interests are minimised in order to ensure decisions are made in the best interests of the public.(52,53)

Vested interests in breast screening

Communication with breast screening consumers is often produced by breast screening providers who are required to meet participation targets. Truthful communication about breast screening may be facilitated by changing the key performance indicators for breast screening services from rates of consumer participation in screening to rates of consumer understanding and participation in shared decision making.(97, 116) It may also be preferable for information to be written by independent experts.(117)

Breast screening policy decisions are often heavily influenced by government or independent experts who review existing evidence and issue comments or guidelines. As in any public health program, experts may have commercial, political or professional interests in a particular outcome that may bias the policy making process. Debates about vested professional interests are a particularly common topic in breast screening. The breast screening evidence is complex and contradictory, and there have been many reviews of the multiple breast screening trials and studies that have presented variable conclusions regarding the benefits and harms associated with breast screening. There has been widespread and public accusation about vested interests of key expert clinicians and researchers with a long history of practice or publication related to breast screening who promote or criticise screening. The declaration of *commercial* interests is a widely accepted tradition, but some writers suggest the principle of transparency also demands that all *professional* interests should be declared (for example, the reputational interests of experts in continuing to defend a long-held position).(118) Some writers advocate that procedural justice requires selecting independent experts as advisors or decision makers, excluding practicing clinicians and academics who have previously published on the topic.(57, 118) Others suggest that all legitimate stakeholders must be involved in decision-making in order to reduce the chance of any one vested interest dominating the process.(53)

Summary: honesty, transparency & procedural justice

- Breast screening communication and decision making may be biased due to vested interests, including professional vested interests, in a particular outcome.
- Honest communications about breast screening may be facilitated by strategies such as removing participation targets or using independent experts.

- Those with professional vested interests could be asked to declare their interests, or be excluded from decision making.

Distributive justice

Distributive justice is about fairness: fairness of opportunity (e.g. the opportunity for all individuals to pursue good health), and fairness of outcome (e.g. everyone in a society achieving at least a basic or threshold level of good health). Achieving justice does not necessarily mean that everyone is treated equally: more effort may need to be expended on some individuals than others in order to attain the same opportunity for, or achievement of, good health. Thus, justice may demand that those with the more limited health opportunities or the poorest predicted health outcomes receive priority.(52,53)

Justice in opportunity

The opportunity for women to attend breast screening remains an important issue. Several barriers to breast screening opportunities have been identified, including geographic, socio-cultural and financial.(80, 119) Many programs have sought to remove or ameliorate these barriers through actions such as: mobile breast screening services, culture and language-specific consumer communication strategies, and reduced cost or free screening. These policies may be expensive, and may bring the principle of justice into conflict with other principles such as delivering the most benefits within available resources.(80)

Justice in health outcomes

Is breast screening a fair strategy in terms of population health outcomes? Certainly breast screening only benefits a minority of the population, but given that people with breast cancer are more likely to have poorer health outcomes, it would seem to be consistent with the principle of justice to expend effort on trying to improve this outcome. Some writers disagree: while breast cancer may affect any woman, it is more common amongst those with higher socio-economic status – that is, women from the group who are, on average, more likely to have good health and opportunities to achieve it. It has been suggested that the breast cancer focus is discriminatory,(37) and a fairer public health system would be one that targets the needs of people who have poorer health outcomes – for example, those with significant social disadvantages or physical disabilities. In this view, a more just approach might be one that focuses less on early detection of breast cancer, and more on providing basic social and health infrastructure for all (for example public transport, a healthy food supply, and affordable treatment services) as well as targeted programs to address the needs of those groups with the worst health outcomes. Notice, though, that this takes for granted that it is reasonable to trade these health-related goods off against one another within a limited health budget. It is likely that many high-income countries could afford both breast screening and interventions to reduce structural disadvantage if they reduced spending in other, arguably less important, policy areas.

Summary: distributive justice

- Many breast screening programs have policies that aim to give all women fair opportunities to attend screening.

- Some writers suggest breast screening makes a relatively small contribution towards the fairness of distribution of health outcomes.

Reciprocity

The principle of reciprocity is generally used to refer to concepts such as returning a favour that is done to us, sharing in carrying public burdens, and supporting and compensating those who carry the heaviest burdens.(120, 121)

Reciprocity, individuals and breast screening

The principle of reciprocity would suggest that individuals who live in and therefore gain health benefits from a society that offers breast screening should be cognisant and supportive of these benefits. In particular, they should not act so as to reduce the opportunity for others to receive similar benefits. This may suggest certain limited obligations for women: for example, to actively attend, cancel or re-schedule appointments so as not to prevent or delay another woman from accessing the service. Whether there is any more substantial reciprocal obligation for women is arguable. We discussed possible corporate benefits of breast screening programs in a previous section (e.g. improved breast cancer treatment). We argued that such benefits, which have already been achieved, are not clearly contingent on women's continued participation. This suggests that individual women should not consider themselves obliged to participate in exchange for these existing corporate benefits. Some might suggest that the existence of a publically-funded healthcare service is a benefit to all, and that in return, citizens should take reasonable care of their health, which includes attending screening services when advised to do so.(33) It is now common in public health generally to

emphasise the importance of individual behaviours,(21, 122) often framed in terms of individual responsibility and duty. This moral language can suggest some kind of reciprocal obligation on individuals. However many would reject this, arguing, for example, that breast screening is not a *necessary* way for a society to demonstrate its commitment to women's health, so women do not have any reciprocal responsibility to participate (or not participate) in breast screening in particular.

Reciprocity is also relevant to breast screening as a driving force in screening advocacy. Individuals who have been diagnosed with illness through screening may feel they have benefited from that program and wish to return the good. Thus the concept of reciprocity may be invoked by screening consumers who seek to “give back” to society through involvement in activities related to screening promotion and advocacy. This is a sensitive issue, particularly if the positions of those advocates, often resolutely pro-screening,(37) seem to ignore more recent evidence about the uncertain balance between benefits and harms of screening.(97) Despite this potential to distort the accuracy of communication, it seems important to recognise the moral value of these advocates' desire to reciprocate, as this provides a stronger basis from which to engage respectfully.

Reciprocity, the state, healthcare systems and breast screening

The principle of reciprocity requires that breast screening programs should seek to minimise disproportionate burdening of any one individual or group of individuals and should support and compensate those who carry burdens, particularly the heaviest burdens. For example, when countries offer organised, publicly funded breast screening, the absence of a financial barrier could be seen as a reciprocal exchange to these women for their status as citizens and

for their willingness to participate in a service that is unlikely to benefit them personally. Screening programs that include free follow-up testing to the point of diagnosis ensure that women who receive false positive tests and thus already carry a disproportionately heavy burden of screening (associated with inevitably imperfect quality control) are not further burdened by financial costs. Privately operated breast screening, by contrast, may simply charge per item. This not only means that women must pay to participate, but also that women who receive false positive screening tests due to limitations of mammography pay more for their screening event than other women. Part of the discomfort that we may feel about this arrangement is likely to be recognition that it contravenes the principle of reciprocity.

Summary: reciprocity

- In a society that offers breast screening, women may be bound by the principle of reciprocity to at least consider screening, and to accept or cancel screening appointments.
- Privately funded screening programs may contravene reciprocity by failing to ameliorate the disproportionate burdens of screening carried by those who receive false positive tests.

Solidarity

Commitment to solidarity has been implicit in public health since its earliest origins, although explicit discussions of solidarity in public health ethics have emerged more recently.(123)

Solidarity is ‘pulling together’ towards a common (collective) cause on the understanding

that there is mutual respect and obligation between members of a community,(124) and a sharing of burdens and threats.(123) There is some overlap between reciprocity and solidarity: both are grounded in ideas about mutual obligation and collective interests.

Solidarity expressed by individuals

Individuals may participate in breast screening for reasons of solidarity – that is, partly to contribute towards benefits for others. Karen Willis (33), for example, has shown empirically that women in rural Australia are motivated to visit mobile breast screening vans partly to show support for healthcare services that may be needed by others in the future. It is possible to recognise the moral value of this expression of solidarity, but question the reasoning that underpins it. In many cases, for example, lack of attendance should not necessarily threaten the viability or continuation of breast screening. Fine-tuning screening according to risk profile may, over time, decrease the perception that participation by low risk women is a valuable expression of solidarity with high risk women.

Uses of solidarity by the state (or by organised screening programs)

Solidarity may be used by the state to justify promotional activities aiming for high breast screening participation rates. That is, while it is recognised that screening will not benefit most people, and will be (mildly, moderately or severely) inconvenient or harmful to many people, it may be acceptable that screening is promoted in order to maintain a politically and economically viable program that delivers large benefits to some.

While the concept of solidarity remains a strong driver for public policy, it is not clear how much burden many members of a society should be expected to shoulder in order to deliver benefit to a few. Some argue that the amount of societal burden attached to breast screening is large and the amount of benefit is small, and it is therefore unreasonable for the state to decide that the public should shoulder that burden. Others argue that the benefits are large and the burdens small, and therefore operating a breast screening program is entirely justifiable. It may be useful to explore community ideas about the importance of solidarity in the context of breast screening; this could be done, for example, by using a citizens' jury to answer the question of whether or not the state is justified in asking people to shoulder the expected burdens of breast screening in order to deliver the predicted level of population benefit.

This way of looking at solidarity and breast screening views breast screening as a topic in isolation. An alternative way of looking at solidarity is to look more generally at population health or even population well-being. At this more holistic level we might ask the question of how we, as a society, should pull together in order to facilitate well-being in others, and consider the impact of a particular policy such as breast screening on the flourishing of the community. This would require a holistic assessment of the extent and distribution of the benefits and burdens of breast screening in the context of other possible health-supporting programs, and deciding how best to recognise the importance of community interests and act for the well-being of each other.

Summary: solidarity

- Individuals may attend, and states may promote, breast screening for reasons of solidarity: while solidarity in itself may have moral value, its use to promote breast screening deserves close scrutiny.
- Prioritising solidarity may require that we consider breast screening in the context of the broadest range of possible health-supporting programs and community interests.

Conclusion

Breast screening is a large public health program with a significant reach. It is not a static entity, but one that varies with time and place. The discussion of contemporary social issues and ethical principles, and how they are relevant in the context of current and future breast screening, adds to and complements biomedical perspectives on this important program.

Armed with this knowledge and understanding, consumers, providers, researchers, and policy makers will be well placed to make an ethical analysis of breast screening: to consider the different ways that principles are being traded off against each other, and to contemplate the extent to which these trade-offs are ethically justifiable. They may identify aspects that could be altered in order to make breast screening a more ethically sound program. Just as the evidence base for healthcare is constantly being updated, social values and institutions change over time. Given the range of social and ethical issues that we have shown to be relevant to breast screening, it seems important to explicitly reconsider these dimensions of breast screening programs when evaluating their success and future. As breast screening continues to evolve in the 21st Century, we expect that social and ethical considerations will be increasingly recognised as critical in policymaking and screening practice.

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Chapter 3: Literature review of empirical studies examining the influences on people's views about breast screening

3.1 Chapter introduction

The central focus of this thesis is the ethical issues relevant to breast cancer screening by mammography. In **Chapter 2** I reviewed the largely theoretical literature about social and ethical issues affecting mammographic screening. In this chapter, I review empirical studies of the factors that influence people's attitudes towards and perceptions of breast screening. I assumed that these attitudes and perceptions would directly inform people's moral evaluations of breast screening, and were thus essential to understanding the ethics of mammographic screening. The questions I sought to answer in this review were:

1. What is the range of reported attitudes towards and perceptions on breast screening by mammography?
2. What influences these attitudes and perceptions?
3. What is the ethical relevance of these attitudes and perceptions?

3.2 Method

Search strategy

Table 3.1 provides an outline of my search (most recently updated in August 2015). I began with database searches on *Medline*, *Embase* and *Scopus* using the MESH terms: "BREAST" or "MAMMOGRAPHY" combined with "MASS SCREENING" and then with "ATTITUDE" or "PERCEPTION". I limited my search to articles published since 1990, reasoning that breast screening became more widely practiced and normalised around that time. I also restricted my search to papers published in the English language, recognising

that this might limit the applicability of my results (see example search string in **Appendix**

6). Initial searching identified 2284 titles.

Table 3.1 Outline of search strategy

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|---|
| <ol style="list-style-type: none">1. Medline, Embase & Scopus database search (see terms above) [2284 titles]2. Application of inclusion and exclusion criteria, removal of duplicates [154 titles]3. Two papers unavailable [152 titles]4. Inclusion of new papers identified through backwards and forwards citations, searching of reference lists [188 titles] |
|---|

I applied inclusion and exclusion criteria to my search (as specified below and in **Appendix 6**) by reading through all titles identified by the database search, and, if the title was insufficiently descriptive, by reading through abstracts. I included empirical studies and reviews published in peer-reviewed academic journals. I only included research that was performed in developed countries with established mammography screening procedures, because I was interested in the influences that are current in these settings, which may be quite different to influences in settings where programs for breast screening by mammography are not yet well established, or where the competing health priorities are very different. In keeping with my focus on mammography screening for women at average risk, I excluded studies focusing on special screening programs for those at high risk. I also excluded studies that specifically concentrated on repeat attendance or non-attendance at breast screening, since I was interested in the broader set of influences, rather than focusing on previous experiences. I only included articles that explored attitudes towards cancer screening more generally if they were explicitly relevant to the topic of breast cancer screening. These inclusion and exclusion criteria are described more fully in **Appendix 6**.

After applying these inclusion and exclusion criteria and removing duplicates, I obtained 154 relevant titles. I reviewed all abstracts and read through full papers that appeared particularly useful for more detailed evaluation. Two titles were not available in abstract or full paper. I then expanded my search by backwards and forwards citation searching of particularly useful or relevant publications; that is, looking (backwards) through the reference list of a publication, and looking (forwards) through the papers that cite that publication. I continued until I was no longer finding new information.¹⁻³ This produced an additional 36 papers. At this point I had identified 188 relevant papers.

Quality of identified papers

The identified papers included both quantitative and qualitative studies. As others have reported, it was difficult to critically compare the methodological quality of such a diverse set of papers,⁴ but my assessment suggested that there were no papers that were clearly inadequate in this domain. For my purposes, issues of methodological quality were relatively less important, as my analysis was focused on the *range* of substantive results, rather than the most significant or important influence/s on screening views, and I was not seeking to perform a quantitative meta-analysis. Thus, while I was interested to identify any quality concerns related to the reporting within a paper of items such as the study's aims, methods and findings,² these were treated as data for analysis, as described below, rather than reasons to exclude a paper. I therefore focused on conceptual rigour for examination of quality, and included all papers that were, by a generous interpretation, conceptually coherent.⁴ **Appendix 7** contains a full list of the papers that I included in my review.

Extraction and analysis of data

Using abstracts and, where necessary or useful, full transcripts, I extracted descriptive and interpretative information from all papers using a series of categories that were established inductively from reading through the papers. I was interested in what each empirical study could contribute towards understanding influences upon people's views about breast screening including: the range of influences studied, the results of each study, and what sorts of claims or arguments were made by the study authors on the basis of their results. I refer to this as the "substantive data" of each paper. I was also interested in more concrete elements of each paper, such as underlying theoretical frameworks, aims and methods. I refer to these items as "meta-data". I read papers and established categories in an iterative fashion, enabling me to crosscheck my developing categories and confirm my reading of findings.^{2,3} The set of categories that I developed for recording meta-data and substantive data from each paper is provided in **Appendix 8**, along with several worked examples of categorised papers.

Many of the papers that I reviewed had an indirect, rather than direct, bearing on my topic. That is, for many studies, the focus was on screening-related behaviour rather than expressed views – for example, researchers might seek to explore the impact of variables such as a woman's level of fear or perceived breast cancer risk on screening participation. Others might work to examine the relationship between gender or speciality of a primary care physician and their screening referral practices. It seems likely that many of the variables being studied in relation to screening behaviour would exert their influence *via* people's views about screening, and indeed some researchers appeared to implicitly acknowledge this by using the participant's self-reported intended behaviour rather than actual behaviour as the end point. In my review of the research results below, I have specified whether the results

were described in relation to actual or intended behaviour. External influences on screening behaviour, such as financial cost or geographic access issues, were also reported on in many studies, but are not the focus of this review.

3.3 Results

188 papers published between 1990 and 2015 were included in my analysis (see **Appendix 7**). My results are reported in sections relating to specified elements of meta-data and substantive data. I begin with describing the location of studied populations and thereafter have ordered my findings largely in keeping with a standard empirical study, discussing my analyses of aims, methods, results and conclusions within the papers that I reviewed. I have altered the standard reporting order where necessary to maintain a more logical flow. For example, I have included discussion of the various underlying theories used in papers in my analysis of methods, rather than as a preliminary to my analysis of aims.

The papers referred to throughout this Results section (which includes **Table 3.2**) are provided as examples relevant to the point being made, and are not intended to be complete reference lists of all papers which might justify that point. The reference list at the end of this chapter contains only those papers to which I have specifically referred; the full list is provided in **Appendix 7**.

Location of studied populations

The substantial majority of identified papers came from studies of people living in North America (mainly the USA but also Canada). The remaining papers derived from research

carried out in the following regions (listed in decreasing numerical order of papers): Europe, Australia/New Zealand, and South-East Asia (Singapore and South Korea).

Aims of reviewed papers

Over three quarters (145/188 papers) of the research had been undertaken for the explicit purpose of increasing participation in mammography screening in order to reduce population breast cancer mortality. Most of these researchers studied the views and behaviours of women, including sub-groups of women who had particularly low screening participation rates or high breast cancer mortality rates, seeking information on who attended, who didn't attend, and why, in order to determine how best to deliver effective breast screening promotion messages. Others studied the views and referral patterns of primary care practitioners in order to identify those who were failing to encourage patients to attend breast screening and should be targeted with educational strategies to enact behaviour change.

A smaller number of studies were performed with a contrasting aim: rather than seeking to promote maximum screening participation in order to deliver benefit, some researchers sought to encourage thoughtful, individualised, and evidence-based screening decision making in order to reduce screening-related harms. A number of researchers studied participants' knowledge about breast screening, seeking to determine whether or not women or practitioners had misconceptions such as overestimation of benefit and underestimation of harms.⁵⁻⁸ Others studied women's decision making processes, exploring the extent to which women might screen or intend to screen for reasons other than an expectation of health benefit.⁹ Some researchers studied primary care practitioners' knowledge and reasoning about screening referrals, again checking for misconceptions about benefit and harm, or for

the influence of factors apart from individualised expectations of patient health outcomes on screening referral patterns.¹⁰⁻¹²

Finally, a handful of researchers explored the sociological phenomenon that is breast cancer screening. They sought to understand the reasons, including social pressures, which lead women to be so enthusiastic about screening. These researchers did not describe an explicit commitment to a particular health or screening agenda.¹³⁻¹⁵

Methods used in reviewed papers

Study design

I identified a mix of study designs in my literature set. Most papers used quantitative methods, such as population surveys with fixed questions and Likert scale answers. A minority used qualitative methods, including semi-structured interviews and focus groups, or mixed methods. Several papers were review articles.

Many of the papers used a deductive methodology, beginning with a hypothesis about factors that were likely to influence ideas and behaviour related to breast screening, and then studying those factors and discussing their relevance and importance in that context. For these papers, the focus of the study (*what* was being studied) was related to the theoretical model that was invoked. Deductive studies often used specific terminology, but as the terminology incorporated vernacular words or phrases that were used inconsistently within and between published papers, there was a wide variance in meanings. (See **Table 3.2.**)

The dominant theory used was the Health Belief Model¹⁶ (HBM). This model, or variants such as the Precede/Proceed framework, was applied to studies of influences on screening behaviour of women and screening referral practices of primary care practitioners¹⁷⁻²¹.

Descriptions of the Health Belief Model varied slightly between different researchers. A common depiction was that the HBM portrayed that a woman's participation in breast screening would be heavily influenced by her beliefs or knowledge about breast cancer (specifically, "perceived breast cancer severity", and "perceived breast cancer susceptibility") and breast screening (specifically, "perceived breast screening benefits" and "perceived barriers" to screening). (Terms in inverted commas are described more fully in **Table 3.2**) These beliefs may be modified by factors such as "fear and/or worry", age, "social values", "cultural values" and experience. The theory suggests that behaviour (that is, whether or not a woman actually participates in screening) will be further influenced by "cues to action" such as discussions with, or advice from significant others. Some researchers also described the HBM model as including a dimension of personal belief in one's ability to participate in screening.^{16, 17, 22, 23} There have been criticisms of the way that the HBM has been used in the study of breast screening behaviour. Yarbrough^{16(p687)} suggests that the HBM is commonly, and incorrectly perceived as a "linear" model, with most researchers failing to explore interactions between HBM variables. Tanner-Smith²³ disapproves of the loss of predictive power that stems from researchers' imprecise use of HBM terminology, something that was also identified in this review. This is explored more fully in the section on terminology, which includes **Table 3.2**.

A second (smaller) group of papers applied a set of related health behaviour theories to women's breast screening actions. These theories suggested that screening practices would

depend heavily on “attitudes” towards screening together with “normative influences” and, in later models at least, perceived levels of control over performing the behaviour. As with the HBM, these models also described indirect influences such as “fear and/or worry”, “social values”, “cultural factors”, and experience. Theories used include the Theory of Reasoned Action^{24, 25} (TRA); the Integrative Model of Behavioural Prediction^{26, 27}; the Model of Planned Behaviour²⁸; and the attitude-social influence-efficacy²⁸ (ASE) model.

A third (even smaller) group of papers referred to the concept of informed decision-making, suggesting that a woman’s views about screening are influenced by her “perceptions of benefits” and “harms”, together with her thoughts about the relative importance of these possible outcomes.^{7, 29-31}

Finally, a handful of papers used a partially or completely inductive methodology, beginning with empirical data about the views of women or primary care practitioners and using this to develop new concepts about how people reason with regard to breast screening, sometimes informed by an existing theoretical lens, such as a feminist perspective.³²

Characteristics of research participants

I identified two groups of people whose attitudes had been studied in some depth: members of the public (166/188 = 88% of the papers) and healthcare practitioners (29/188 = 15% of the papers). Five papers reported on both groups. Most of the research involving members of the public focused on women, but some of the research that looked at attitudes towards cancer screening more generally included men in the sample population. One study compared the attitudes of women with the attitudes of men.³³ Almost half (80/166 papers) of

the research involving women focused on specific sub-groups of women. Researchers described women in these particular sub-groups as though they were different from the mainstream in some way; for example, due to a particular ethnicity, socio-economic status, age, or level of urbanisation. Sometimes several of these characteristics were combined; for example, one research group recruited women described by the terms “low-income”, “elderly (60+)”, “urban” and “minority” (primarily African-American).³⁴

The research involving healthcare practitioners focused exclusively on clinicians providing primary care. The range of clinicians studied varied depending on the organisation of healthcare in the relevant country. For example, studies from the UK and Canada looked at the attitudes of general practitioners (described as family physicians in Canada),³⁵⁻³⁷ while studies from USA included general practitioners, family physicians, obstetrician-gynaecologists and general internal medicine physicians,^{20, 38-41} with one study also including nurse practitioners.⁴² Henceforth I use the terms “primary care practitioners” to include these groups of study participants.

There were no papers studying the views of people who make or influence breast screening policies and practices, such as: prominent clinicians and researchers working in the field; senior figures in breast screening administration and policy; and leaders in breast screening advocacy. There are a wide variety of breast screening protocols promulgated by government and non-government bodies throughout the countries included in my review, protocols that are written or influenced by prominent figures working in one or more of the fields mentioned above. Given that these protocols significantly constrain what women and primary care practitioners can do in relation to breast screening, it would seem important to

explore the views of these prominent figures and critically analyse the factors that influences their views. The lack of any research into this group was identified as a noteworthy gap in the literature.

Terminology used in empirical studies

There was substantial variation in the terminologies used amongst the different empirical studies, as depicted in **Table 3.2**. Although many researchers explained their terminology in the text of their paper, this was not universal. Terminology was often used by different researchers to describe different concepts. For example many researchers used the term “perceived susceptibility”⁴³ in relation to breast cancer to mean the self-rated likelihood of getting breast cancer, but some researchers used the term more specifically, such as by detailing a time frame (e.g. ten or eleven years,³¹ or lifetime^{44,45}) or by using it to mean likelihood of getting breast cancer in comparison to others, such as women of a similar age, ethnicity or other women in general.⁴⁵⁻⁴⁷ Other studies used the terminology more broadly, incorporating into its meaning one or more additional, related concepts such as self-rated likelihood of dying from breast cancer.^{7,44}

In addition to this, a single concept was described by a variety of terms, sometimes in the same paper. For example, the self-rated likelihood of getting breast cancer was also described by the terms “perceived risk”,^{48,49} “subjective risk”,²⁹ “perceived vulnerability”,⁴⁹ and “perceived probability”.⁴⁴ Some researchers used new terminology for specific concepts, for example “comparative risk”, to describe perceived susceptibility compared to others.⁴⁸

(See table overleaf)

Table 3.2 Terminology variance: the range of what researchers mean when using specific words or phrases to describe frequently studied variables^a

<i>Main definition</i>	<i>Alternative definitions</i>	<i>Alternative terms for main definition</i>	<i>Notes</i>
Perceived susceptibility⁴³ (HBM^b terminology)			
Self-rated likelihood of getting (i.e. being diagnosed with) breast cancer ⁴³	Sometimes more specific: certain time frame (e.g. next 10 years) ³¹ ; lifetime risk ^{44, 45} ; relative to certain group e.g. peers, own-age peers, women of similar ethnic background. ^{29, 45, 47} Sometimes described in terms of perceived risk factors. ^{17, 5} Sometimes bundled up with <i>fear and/or worry^c</i> , as in: perceived susceptibility = self rated likelihood of developing breast cancer and how worried one is about it. ³¹ Sometimes includes self-rated likelihood of dying from breast cancer. ^{7, 44}	Perceived risk; ⁴⁸ perceived vulnerability; ⁴⁹ subjective risk; ²⁹ perceived probability. ⁴⁴	Often compared with researcher's perceptions of consumer susceptibility, which is described as: objective; ⁴⁸ actual; ⁵¹ factual; ⁵² accurate; ⁵² calculated; ⁴⁶ epidemiological; ¹⁵ clinical. ^{13, 53}
Perceived severity⁴³ (HBM terminology)			
Self-rated likelihood of death, pain, suffering to result from a breast cancer diagnosis ⁴³	Perceived severity of treatment and likelihood of losing affected breast. ^{17, 50}	Perceived seriousness. ⁵⁴	Not commonly studied; some researchers explicitly suggest that (self) perceived severity is always high; ¹⁷ not used as a synonym for <i>perceived treatment efficacy</i> .
Perceived benefits^{6, 55, 56} (HBM terminology)			
Perceived extent to which participation in screening will: reduce one's likelihood of dying from breast cancer ^{17, 31, 55} and/or reduce population breast cancer mortality ^{6, 29}	Sometimes includes one or more of: reassurance that one does not have breast cancer; ⁵⁷⁻⁵⁹ increased curability of breast cancer. ¹⁸ Sometimes includes perceived likelihood that screening will: detect breast cancer if it is present; ^{17, 58, 60} reduce severity of required treatment in the event that breast cancer is detected; ^{17, 59} be a simple process; ¹⁷ contribute to a sense of self control over own health; ^{17, 29} reduce anticipated regret; ⁶¹ fulfil a perceived moral obligation. ²⁸	Knowledge of benefits; ⁶ beliefs about screening; ⁶² attitudes about screening; ⁶² perceived usefulness; ⁶³ perceived screening efficacy; ^{7, 46} screening effectiveness; ^{18, 44} appreciation of the value of screening; ^{61, 64} predictive value of screening; ⁷ advantages; ⁶³ pros. ⁶⁵	Often compared with researcher's perceptions of benefit, described as: realistic; ⁶ accurate; ⁵⁵ calculated; ^{29, 44} epidemiological. ¹⁵ Consumer perceptions that do not match researcher's perceptions are described as: inaccurate; ⁴⁶ not realistic; ⁴⁶ ill informed; ⁸ misconceptions; ⁴⁶ over/underestimates; ^{8, 46} causing unwarranted optimism. ⁴⁶

Table continued overleaf

Main definition	Alternative definitions	Alternative terms for main definition	Notes
Perceived barriers ⁶⁶ (HBM terminology)			
Instrumental issues that might prevent a woman who would otherwise be keen to participate in screening from doing so e.g. cost; time; access; lack of awareness. ^{18, 67}	Sometimes includes one or more of: lack of physician referral; ^{16, 24} past (negative) experience; ²⁴ degree of concern about expected level of pain and/or embarrassment; ^{16, 67} fear of finding breast cancer; ^{67, 68} perceived likelihood of breast damage due to pressure and/or radiation; ²⁵ lack of perceived susceptibility; ^{24, 54} low perceived screening accuracy ⁶⁸ or effectiveness. ⁶³ Sometimes includes cultural values [see below] such as concerns about breast privacy.	Constraints. ²⁴	May be compared to screening facilitators e.g. receiving a mammogram appointment time; doctor ordering a mammogram. ²⁴ Some overlap with harms .
Beliefs and/or knowledge ⁶⁰ (HBM terminology)			
“Beliefs” and “knowledge” are used interchangeably. They are used as alternative terms for perceived susceptibility ^{46, 48} and/or perceived benefit ^{6, 46} .	Sometimes includes one or more of: perceived severity ¹⁷ ; breast screening knowledge ⁶⁰ ; breast cancer knowledge ¹⁷ ; harms ⁶⁶ .	Cognitive variables; ⁶² perceptions and knowledge. ⁵⁰	Frequent overlap between: knowledge ; breast screening knowledge ; breast cancer knowledge .
Breast screening knowledge and/or beliefs ⁵⁰ (this terminology is widely used across different research theories)			
Awareness that breast screening exists ⁶⁹ and/or knowledge about screening guidelines (e.g. starting age; frequency; finishing age). ^{19, 63}	Sometimes includes one or more of: how to access screening; ⁵⁰ perceived benefits ⁶⁰ ; harms ²¹ ; some aspects of breast cancer knowledge ¹⁷ .	Enabling factors; ¹⁸ breast health beliefs; ⁶⁶ general knowledge; ⁵¹ behavioural beliefs. ²⁴	Frequent overlap between: knowledge ; breast screening knowledge ; breast cancer knowledge .

Table continued overleaf

Main definition	Alternative definitions	Alternative terms for main definition	Notes
Breast cancer knowledge and/or beliefs ⁶¹ (this terminology is widely used across different research theories)			
A set of beliefs about breast cancer; there is no clear main definition that denotes which beliefs are included in the set.	One or more of: beliefs about natural history of breast cancer (e.g. beliefs about causes of breast cancer, links between early diagnosis and longer survival, awareness of asymptomatic disease, awareness of non-progressive disease); ^{61, 69, 70} perceived susceptibility particularly in terms of beliefs about risk factors; ^{21, 61, 62, 71} perceived screening efficacy ⁷ ; perceived severity ⁵⁴ ; perceived treatment efficacy ⁶² ; breast screening knowledge ⁶⁶	Breast cancer perceptions; ^{63, 70} health concepts. ⁶⁴	Often used to refer to beliefs of mainstream communities. Beliefs that are common to a specified ethnic subgroup are often described as traditional and cultural health beliefs although there is some overlap. Frequent overlap between: knowledge; breast screening knowledge; breast cancer knowledge . May be compared with researcher's breast cancer knowledge which is described as: accurate or correct. ^{8, 46}
Traditional and cultural health beliefs ⁶⁹ (this terminology is widely used across different research theories and also used without reference to specific theories)			
The set of beliefs about breast cancer and health in general that are common to specified ethnic subgroups. ⁶⁹	One or more of: belief that breast cancer is always fatal; ⁶⁹ belief that breast cancer cannot be detected if there are no palpable lumps; ⁶⁹ belief that talking or thinking about breast cancer might result in ill-health; ⁷² belief that good health outcomes will follow from holistic self-care rather than specific interventions such as breast screening. ²¹ May include one or more moral values applied to screening as described in cultural values . ^{73, 74}	Fatalism; ^{43, 50, 72} traditional concepts of health and health promotion; ⁶⁴ cultural beliefs and traditions; ⁵⁰ cultural beliefs and values. ⁷⁴	Overlaps with breast cancer knowledge and cultural factors .

Table continued overleaf

Main definition	Alternative definitions	Alternative terms for main definition	Notes
Attitude ¹⁷ (TRA ^d terminology; also used without reference to specific theories)			
Perceived balance of benefits & harms; determined by perceived benefits and perceived harms and the woman's evaluation of how positive or negative these outcomes are for her own situation. ^{24, 46}	Screening intentions, ^{31, 46} whether or not screening is considered necessary or unnecessary, ²¹ degree to which mammography is considered the screening method most likely to maximise health outcomes (e.g. compared to clinical examination or self examination). ⁴³ Sometimes includes: perceived susceptibility ; fear and/or worry ²⁴ including anticipated regret; ²⁸ social values including perceived moral obligation to screen. ²⁸ Occasionally used to mean the attitude towards the balance of benefits and harms of breast screening at a community level. ⁵⁶ Sometimes used interchangeably or in conjunction with breast screening knowledge, beliefs (e.g. as in "beliefs and attitudes towards breast screening") and may, in this context, be a synonym for beliefs. ^{43, 62}	Perception; ⁵⁶ value judgement; ^{31, 75} personal decision; ³¹ preference. ⁷	May be considered part of informed decision making . ^{7, 46, 55} May be described as favourable/unfavourable towards screening. ⁴⁶
Fear and/or worry ⁴⁹ (this terminology is alluded to in HBM, TRA & ASE ^c and also used without reference to specific theories)			
Concerns focussing on one or more of: breast cancer (non-specific); ⁴⁹ process of screening (specifically in relation to harms of: embarrassment; pain; damage from radiation or pressure); ⁵⁸ having a breast cancer diagnosis. ³¹	Generalised tendencies towards anxiety, depression and patterns of emotional regulation. ⁶² Sometimes grouped with normative influences . ⁶²	Anxiety; ⁶² emotion; ⁴⁸ emotional barriers; ¹⁷ affective construct; ^{31, 45} psychosocial or socio-emotional variables (when grouped with normative influences). ⁶²	Considine ⁷⁶ suggests that the focus and level of fear and/or worry may affect their influence on screening behaviour. She argues that one reason for conflicting evidence about the impact of fear and/or worry is the use of non-specific terminology and a subsequent inability to effectively compare results. She advises future researchers to be more specific about their focus and to study the impact of different levels (e.g. high, medium or low) of fear and/or worry .

Table continued overleaf

Main definition	Alternative definitions	Alternative terms for main definition	Notes
Influences of others			
Perception of views of significant others (e.g. family, friends, primary care practitioners) about whether or not one should get screened. ^{18, 24, 26, 58}	May include perceived behaviour of significant others – i.e. whether or not significant others get screened. ²⁶	Subjective norms (TRA terminology); ^{24, 26, 58} normative pressures; ²⁶ normative beliefs; ²⁴ social norms; ²⁷ social network patterns; ^{27, 62} social relations; ⁶² social influences; ²⁸ cue to action (HBM terminology). ¹⁸	Smith-McLallen ²⁶ suggests that, in practice, subjective norms (also described by him as <i>normative pressures</i>) include both the perceived views of others (so-called <i>injunctive norms</i>) and the behaviour of others (<i>descriptive norms</i>). He goes on to suggest that many researchers only study injunctive norms, and this might be why subjective norms are often found to be of limited influence. He advises that researchers should ensure that they also study descriptive norms.
Harms^{31, 61} (IDM^f terminology and also used without reference to specific theories)			
Either or both of two grouped outcomes: [1] pain, discomfort, embarrassment, concern about damage from pressure and/or radiation; ^{58, 77} [2] false positive diagnoses, overdiagnosis. ⁷⁵	Sometimes includes false negative diagnoses. ⁶¹ Sometimes refers to the perceived likelihood of harms occurring. ³¹	Risks; ⁷⁸ downsides; ⁵⁶ negative consequences; ⁵⁸ limitations; ⁵⁷ cons; ⁶⁵ drawbacks. ⁶⁵ Sometimes definitions [1] and [2] are described separately, for example, [1] = “perceived harms” or “minor inconveniences”, and [2] = “serious harms” or “important problems”. ^{65, 75}	Some overlap with <i>perceived barriers</i> . ^{17, 25}

Table continued overleaf

Main definition	Alternative definitions	Alternative terms for main definition	Notes
Informed decision making ^{7, 31} (IDM terminology)			
Decision making that is determined by the woman's response to "accurate" (i.e. that match researcher's perceptions) knowledge about likely benefits and harms. ^{8, 29}	Sometimes includes one or more of: "accurate" perception (i.e. matches researcher's perception) of the woman's breast cancer susceptibility; ⁴⁴ the woman's careful consideration; ⁷⁵ the woman's participation in decision making to the extent that she wishes; ³¹ behavioural implementation. ⁵⁷	(Truly) informed consent; ⁶⁵ informed choice. ⁷⁵	The woman's decisional response to the information may be described as her "preference" ⁷⁷ [see <i>attitude</i> above].
Cultural values ⁵⁰ (this terminology is alluded to in HBM, TRA, ASE and also used without reference to specific theories)			
One or more of various ethical values held by a woman that affect her views about screening and that are common to an identified ethnic subgroup. ⁵⁰	Ethical values may include the degree to which the following are considered to be right or wrong, largely independent of health outcomes: active pursuit of early diagnosis of disease; ⁶⁴ breast privacy; ⁵⁰ active protection and promotion of one's own health. ⁵⁰	Cultural attitudes and traditions; ^{32, 50} cultural factors; ⁶⁹ concerns. ²⁵ May be grouped together with, and described as <i>traditional and cultural health beliefs</i> ^{73, 74} or variant of that phrase.	May overlap with <i>traditional and cultural health beliefs</i> ⁶⁷ and with <i>social values</i> . More commonly studied than <i>social values</i> .

Table continued overleaf

<i>Main definition</i>	<i>Alternative definitions</i>	<i>Alternative terms for main definition</i>	<i>Notes</i>
Social values ¹⁵ (this terminology is alluded to in HBM, TRA, ASE and also used without reference to specific theories)			
One or more of various ethical values held by a woman that affect her views about screening and are dominant within mainstream society. ^{15, 53}	Ethical values may include those described in <i>cultural values</i> plus one or more of the degree to which a woman considers the following to be right or wrong, largely independent of health outcomes: taking personal responsibility for health; ^{79, 80} active surveillance, regularly attending screening; ¹⁴ having knowledge about one's breast health or disease; ⁶¹ using technology; ^{14, 15} attending screening in order to protect services for future women; ¹⁵ attending screening because it is offered as a healthcare service; ⁷⁹ (for a government to be) providing healthcare choices to citizens. ⁷⁹	A variety of two-word descriptors containing an adjective and a noun. Adjectives include: socio-structural; cultural; political; ideological; relational; moral; psychosocial. Nouns include: factors; reasoning; obligations; identities; beliefs; ideas; mechanisms. ^{9, 14, 15, 28, 53, 77, 79, 80} Also: meanings that women attach to mammograms; ⁷⁹ lay perceptions or considerations or concepts of risk, ¹³ choice, trust, health. ¹⁴	Note that there is some overlap of terminology with <i>cultural values</i> . ⁵³

NOTE: as with the main text in this chapter, references are provided as examples relevant to the point being made, and are not intended to be complete reference lists. ***Black italics*** are used when cross-referencing to terms that are described in this table. HBM = Health Belief Model; TRA = Theory of Reasoned Action; ASE = Attitude-Social influence-Efficacy model; IDM = Informed decision making concept.

Results reported in reviewed papers

The views and reasoning of women

The empirical research studied and described a variety of factors influencing the way that women reason about breast screening and come to hold the views that they do. I have collated these factors loosely into three categories: health beliefs, other psychological factors and ethical values. Where I have used specific terminology I use it to mean the “main definition” as described in **Table 3.2**. I have focused on providing the range of influences that researchers consider to be relevant to people’s views on breast screening; I have not attempted to estimate the importance or prevalence of one or more defined variables upon views or screening behaviour.^{62, 66, 76} Some researchers studied one or more factors as though they were independent variables,²⁴ others described factors as being more or less interrelated with each other.¹⁶

Women’s health beliefs

I use this term collectively to refer to any or all of the variables discussed below. These factors were the most frequently studied,⁶² possibly because many of them are central concepts in the HBM, which was widely used.

Perceived susceptibility

Women who perceived themselves as being highly susceptible to breast cancer were more likely to participate or intend to participate in mammography screening than women who perceived themselves with low susceptibility (for example^{17, 31, 48, 49, 58, 62, 68}). This may

indicate that women's views towards mammography are influenced by their perceived risk, although many researchers note that since most studies are cross-sectional a cause-and-effect relationship cannot be assumed. Other explanations for the noted relationship may be: women who participate in screening develop higher perceptions of vulnerability,^{45, 49} or women who do indeed have higher risk (for example, due to a positive family history of breast cancer) are more likely to be encouraged by their primary care practitioner to attend screening.⁴⁹

Perceived severity of breast cancer

Despite its central position in the HBM, this factor was not as commonly studied as some other aspects of knowledge, perhaps because it was not found to be a discriminating factor. For example, it may have been that most women perceived breast cancer to be a severe disease.¹⁷ When it was studied some researchers found that perceived breast cancer severity was positively associated with screening⁴³ and also linked with higher perceived risk.³¹

Perceived benefits

The degree to which women believed that breast screening would reduce their own likelihood of dying from breast cancer, or reduce population breast cancer mortality, was found by many researchers to be associated with the level of screening attendance or intention to screen (for example^{7, 8, 17, 31, 60, 62, 78}). Despite this, at least one researcher noted that some women did not think themselves to be influenced by information about mortality benefits.⁵⁷ Many researchers found that women were influenced by a perceived benefit that participating in screening would deliver reassurance that they do not, at least at present, have breast cancer

(for example⁵⁷⁻⁵⁹) or would reduce their need for aggressive treatment if they did have cancer.⁵⁹

Knowledge about breast screening practices and policies

This was not commonly studied, possibly because it was thought to be relatively obvious, but some researchers did find that women were more likely to screen if they had better awareness of and knowledge about mammography screening protocols and how to access screening.⁵⁰

Knowledge about breast cancer

Aside from the relative lack of research around perceived breast cancer severity, as discussed above, the influence of women's knowledge about breast cancer was widely studied. For example, it was frequently shown that those who believed breast cancer could not exist in the absence of a palpable lump were less likely to attend screening than those who believed cancer could be present in the absence of symptoms.^{18, 32, 64, 79} Similarly, women who believed that breast cancer was untreatable were less likely to screen than those who believed that breast cancer was curable with treatment, particularly if found "early".^{17, 18, 50, 62}

General health knowledge was also found to influence screening. For example, women who believed that health problems were always unpredictable and simply had to be accepted and dealt with were less likely to screen than those who saw health as something that was at least partly under one's control.^{53, 63, 79} Women who believed that ill-health could be caused by negative thoughts, including thoughts about disease, were less likely to screen.⁶⁴

Harms of screening

Harms were often discussed as grouped elements, as shown in **Table 3.2**. Many researchers studied harms described in terms of self-rated likelihood of: a woman suffering due to pain, discomfort, embarrassment or anticipatory anxiety associated with mammography; and breast damage arising from the pressure and/or radiation. (The descriptor “perceived” was less commonly used in relation to harms than benefits, although it would seem to be similarly applicable.) Researchers found that high levels of (perceived) harms of these sort were associated with negative views about screening and lower screening participation or referral rates.^{17, 58}

A smaller number of researchers studied harms described in terms of self-perceived or researcher-perceived rates of false positive results and overdiagnosis. Most researchers studying these kinds of harms were interested in the implications for Informed Decision Making (IDM); they found limited influence of these harms on people’s views, unless the perceived level of harm was very high.^{57, 75, 78}

I also examined how researchers compared women’s health beliefs with researchers’ beliefs. Women’s beliefs were often described as being at variance with what researchers believed (where the latter were taken to be correct). For example, it was frequently shown that women’s perceptions of breast screening benefit were higher than the researchers’ perceptions,^{6, 8, 29} and that women’s perceptions of harms were lower.^{56, 61} Researchers also noted predictable patterns of knowledge among different women according to discernable factors such as a woman’s culture and experiences. For example, Chinese women living in Australia were less likely to believe that breast cancer could be asymptomatic than women

described by the authors as being “white Australian women”,⁶⁴ and Hispanic women in America were more likely to believe that breast cancer is always fatal than so-called “white Americans”.⁵⁰ Women who had friends with cancer, particularly breast cancer, were likely to have a higher perceived susceptibility than those without.^{21, 77}

The literature also studied the impact of normative influences, with results suggesting that advice from a woman’s primary care practitioner to participate in screening^{18, 24, 66} or the screening practices and attitudes of peers and family^{17, 18, 24, 27, 58, 81, 82} influence women’s screening behaviour. Researchers noted that it was not clear how these operate – for example, it may be that normative pressures change a woman’s knowledge (“my doctor tells me to go - so I must be susceptible”, or “my friends go - so screening must be beneficial”). Alternatively these pressures may act via relational forces (“I want to belong to this peer group so I will think the same way that they do about screening”) or may simply trigger behavioural action (“I already felt positive about going to screening, your comment has just reminded me to go”). Women’s knowledge was also found to interact with psychological factors; in particular, greater anxiety was associated with higher perceived susceptibility.^{31, 48}

Psychological factors

Psychological factors outside of the health beliefs discussed above were studied less frequently. Researchers studied the relationship between screening intentions or behaviour, and one or both of: psychological responses to breast cancer, and psychological responses to breast screening. Most studies explored responses described as fear, worry or anxiety; a few studies looked at other responses, such as apathy, denial, shame, embarrassment or anticipated regret.^{28, 43, 52, 61}

Women themselves frequently cite the desire for reassurance as a major reason for screening or intending to screen,^{14, 31, 59, 75, 78, 80} but the empirical studies looking at associations between psychological factors and screening produced contradictory results.⁸³ This may have been at least partly due to a lack of specificity about terminology.^{58, 76} It was not always clear, for example, whether a study was exploring a woman's anxiety about the process of breast screening, the idea of having a breast cancer diagnosis, or about breast cancer more generally. These distinctions are, arguably, relevant, since the former may influence a woman to view screening negatively^{17, 63} while the latter two may influence a woman to be more positive about screening. It was also suggested that the level of emotional response may be relevant: in particular, some studies have found that while moderately high levels of fear about a breast cancer diagnosis are associated with increased screening or screening intentions, extremely high levels of fear have the opposite effect.^{58, 76}

Researchers found an association between psychological responses and social or cultural values. Many studies noted that women belonging to certain cultures were more likely than others to have strong emotions of shame or embarrassment about the process of breast screening stemming from particular values about exposing their breasts to others (for example^{52, 59}). Similarly, women who believed that their breast appearance did not conform to their perceived norm of physical attractiveness were more likely to feel embarrassed about the idea of screening.⁵²

Ethical values

Some researchers studied women's views about breast screening within a broader context of social and cultural values and behaviours.¹⁴ These researchers did not necessarily think of themselves as studying ethics or values, but their findings are relevant to understanding the extent to which a woman's ideas about what is right and wrong might influence what they think or do about breast screening. This research most frequently took the form of studying what was said or done in relation to breast cancer or breast screening among women belonging to a specific cultural subgroup, and comparing the results, either explicitly or implicitly, to the more populous or apparently mainstream cultural group. For example, the talk and behaviour of African-American, Hispanic, Chinese, Indian or Korean women living in the USA, Canada, UK or Australia were studied and compared with the comments or behaviour of Caucasian women living in the same country (for example^{50, 64}). Less commonly, the talk or behaviour of non-Caucasian women living in their own countries was studied, for example, South Korean women living in South Korea.³² In the process of studying women in this way, researchers discussed one or more ethical values held by the subgroup under scrutiny as being likely to influence their views or behaviour about breast screening. That is, researchers suggested that certain culturally held values about what was right or wrong influenced a woman's thinking about breast screening. The term "ethics" was never explicitly used; such ideas were commonly referred to as "cultural factors" or "values" (see **Table 3.2**).

The kinds of values that these researchers studied and described as being relevant to breast screening included the extent to which a woman considers it right or wrong to: actively pursue disease, allow her breasts to be seen by a healthcare worker, or take particular interest

in her own health. For example, some cultural groups reportedly consider breast screening to be wrong because a woman should prioritise her family's health, not her own.⁵⁰ Others such as traditional Chinese communities allegedly see the maintenance and pursuit of personal good health as being morally admirable, but regard the correct approach as being holistic self-care such as attention to sleep, psychological wellbeing and diet, and consider that actively seeking out disease through screening is wrong ("looking for trouble").⁶⁴

Other researchers concentrated only on the most populous or apparently mainstream cultural group, studying the variety of ways that women spoke in terms of their assumptions and perceived obligations around breast screening and breast cancer.^{9, 15, 28, 53, 77, 79, 80} Although the term "ethics" was never used some researchers described their findings with explicit reference to ethics, using phrases such as "moral reasoning",^{15, 79} "the right thing to do"⁹ and "social values".¹⁵ Others described similar concepts with more oblique phrases such as "psychosocial factors"⁷⁷ or wrote about moral elements in risk and risk avoidance (see **Table 3.2**).^{13, 53, 84} These researchers discussed and described the influence of one or more of a wide range of values. In particular, their results suggest that women's sense of personal moral responsibility for their health often influences their views about breast screening by mammogram.^{15, 80} The steps involved in women's reasoning might proceed as follows (although are rarely stated so explicitly): 'pursuit of good personal health is right and responsible behaviour; early diagnosis of a breast cancer might give me a better health outcome; breast screening by mammography gives me the best chance of early diagnosis of a breast cancer; *therefore* breast screening by mammography is right and responsible behaviour'. The moralistic phrase, "better safe than sorry", transcribed by several researchers

as a common form of women's discussion about breast screening,^{61, 77} might reflect a truncated version of the reasoning process described above.

Other values were also found to be important. The degree to which women valued science and technology influenced their views on screening: women who placed a high degree of value in technology and scientific or medical expertise were likely to have more positive attitudes towards mammographic screening than women who placed higher value on their own abilities to detect abnormalities or care for their breast health.^{53, 84} Similarly women who valued knowledge about their breast (patho)physiology in its own right, apparently unrelated to the health outcomes of that knowledge, were likely to be supportive of screening.^{61, 75, 78}

Some women, for example, wanted to be screened for indolent breast cancer that would never cause a problem.⁹ As described in **Chapter 2**, certain women wanted to participate in breast screening because they thought it important to support the service so that it, and other healthcare services, would remain viable and available for others to use, or at least to consider using.^{15, 78, 79} For these women, it appeared to be the availability of healthcare choices that was of importance. Other researchers described the influence of the concept of reciprocity, suggesting that some women felt it important to attend breast screening services at least partly because they had been made available to them.⁷⁹ Finally, some women appeared to have a general concept that regular participation in breast screening was morally admirable, without necessarily specifying why this might be so.⁸⁰

Primary care practitioners

The views and reasoning of primary care practitioners in relation to breast screening have been studied far less than the views of women. The studies included in this review assumed

that the view of a woman's primary care practitioner towards screening mammography was an important factor influencing her decision to screen or not screen. Researchers were seeking to understand why a primary care practitioner would or would not refer a patient to breast screening. The factors studied in primary care practitioners showed similarities and differences to those studied in women. Many researchers explored practitioners' knowledge about breast cancer or breast screening but there were very few studies of primary care practitioners that focused on psychological or ethical dimensions of their views.

Researchers studying the knowledge of primary care practitioners focused on their knowledge of the natural history of breast cancer, risk factors,³⁶ breast screening benefits^{12, 36, 39, 85, 86} and breast screening harms.^{36, 85-87} Most primary care practitioners believed that benefits outweighed harms, and were enthusiastic supporters of breast screening (for example^{36, 88}). Others were concerned about harms, particularly for subpopulations of women in their practice such as those under 50 years or older than 69 years.^{12, 85, 87}

Several studies found that primary care practitioners' knowledge was out of step with what the researchers themselves believed. For example, some primary care practitioners considered that women with very limited life expectancies would derive benefit from breast screening.^{11, 12} American researchers who studied primary care practitioners from a variety of specialties noted that knowledge about breast screening benefits was influenced by the primary care practitioners' specialty. In particular, obstetrician-gynaecologists tended to perceived higher breast screening efficacy than primary care practitioners from other specialties.^{10, 12, 89}

There were no studies that explored possible influences of psychological factors, such as fear or anxiety about breast cancer, on primary care practitioners' breast screening views or referral practices. Several studies explored the association between the primary care practitioner's gender and their views, referral practices, or personal behaviour with regard to breast screening.^{35, 39, 41, 88} The results were contradictory, although at least two studies found that female primary care practitioners were more likely to refer patients for breast screening.^{39, 88} One of these studies also found that female primary care practitioners were more likely to believe that breast screening was a "very effective" test^{39p38} suggesting that health beliefs may be at least part of the mechanism for gender differences.

Researchers noted the influence of normative pressures upon the breast screening referral patterns of primary care practitioners. Normative pressures included perceptions about the views or referral practices of colleagues, experts and mentors, as well as the perceived expectations of women. In particular, primary care practitioners were more likely to follow screening guidelines that were promoted by their speciality organisation. Normative pressures may have acted partly by changing primary care practitioners' knowledge about screening (as suggested above regarding the association between practitioner specialty and perceived screening efficacy), but may also have affected screening referral patterns by other means such as concerns about litigation^{20, 87} or responding to patient demands for other reasons.^{40, 90} Many studies noted that primary care practitioners' attitude towards screening mammography did not necessarily predict their recommendations to patients.^{10, 12, 87} There is a large literature exploring the reasons why there might be a disconnect between what healthcare practitioners think and what they do.⁹¹⁻⁹³

Only one researcher mentioned the influence of ethical values that were not explicitly about health outcomes. Smith⁸⁵ found that some physicians were positive about the availability of screening mammography or encouraging awareness about screening because they saw such policies as being respectful of their patients' autonomy.

Concluding arguments made in empirical papers

The research conclusions were narrowly focused on a defined number of topics. These tended to be closely related, as might be expected, to the stated aims of the papers. Most of the studies used their results to suggest that particular interventions would increase breast screening participation rates, and concluded by arguing that those interventions should therefore be put in place. For example, several papers argued in favour of using promotional activities to increase normative influences to screen, such as: broadcasting the messages that most women participate in screening²⁷ or that most women find their family and friends would want them to attend breast screening,²⁴ explicitly encouraging friends and family to express approval of breast screening,^{27, 50, 58} and using a range of culturally-specific female models in screening educational and promotional material.⁶⁴ Others targeted primary care practitioners, suggesting that they should be encouraged and reminded to regularly discuss and promote breast screening (for example^{17, 18, 20, 24, 41, 42, 58}) and should be educated to understand and explicitly address a woman's fears or particular cultural values that may be negatively influencing her views about screening.^{18, 50, 58, 69, 73} Some papers called for more research into the ways that psychological factors and ethical values influence women, so that they could be better understood and harnessed for promotional activities.^{48, 62}

Many of those researchers who aimed to reduce excessive harms through the facilitation of better-informed and more individualised decision making drew attention to their results showing the knowledge inaccuracies amongst women or primary care practitioners, and concluded by arguing for greater efforts to ensure correct knowledge. Suggestions included: informing about harms and correcting misconceptions about benefits,^{6, 8, 9, 44, 46, 56, 61, 75} using particular communication elements such as absolute risk figures and decision aids,^{7, 55} and further research into how to best communicate the complexities of overdiagnosis.⁷⁸ Other researchers argued for primary care practitioners to focus on individual patient considerations, rather than rely on standardised guidelines for screening advice.¹² One researcher concluded with a competing argument, emphasising that since older women were reluctant to consider the impact of their own (limited) life expectancy on screening benefits even when this information was provided to them, an IDM approach would lead to overuse of screening amongst those unlikely to benefit and therefore should *not* be used for breast screening with older women.³⁰

The smaller number of researchers whose aims were to contribute to better understanding of social factors operating in breast screening used their results to argue for wider acknowledgement of the influence that non-health maximising factors have upon women's screening views and actions. They particularly argued for a wider recognition of the impact of breast screening policies on women's breast screening views.^{13, 15, 80}

3.4 Discussion

This review of the empirical literature about factors that influence people's views on breast screening showed a heavy research focus on the health beliefs of women and primary care practitioners. This included substantial study of culturally specific health beliefs amongst women. Such research rested upon and has potentially reinforced widespread acceptance of theoretical models that suggest the health beliefs of women and primary care practitioners are important influences on their views about breast screening, and are therefore suitable targets for activities aimed at influencing screening related behaviour or decision making.

This review also revealed some important limitations in the existing body of empirical research. The use of terminology in this field was inconsistent and potentially misleading. There was limited research into the impact of psychological and ethical factors on people's views about screening and I found no empirical research at all into the views of people who were involved in making or influencing breast screening policy and practice.

While it was known that people who make or influence breast screening policy and practice hold different views about screening (for example,⁹⁴ and paired articles presenting competing views^{95,96}), I identified a gap in the literature relating to the lack of empirical research into these views or the factors that might influence them. In the same way that it was, and still is, widely assumed that women's views are predominantly based on health beliefs, it may have been assumed that differences amongst the views of these influential people were predominantly based upon variations in their beliefs about breast cancer and breast screening. Given, however, that many of those with policy and practice influence would be leaders in their field, it seemed less plausible that such people would hold the kinds of health beliefs

sometimes described in women as “inaccurate” or “ill informed” (see **Table 3.2**). There was no research, however, to back up or refute such assumptions, or to investigate alternative reasons as to why these influential people might hold different beliefs.

The limited research focus on factors outside of health beliefs had been noted previously. Other reviewers noted and questioned the dominating influence of the Health Belief Model model in the research and understanding of women’s breast screening behaviour, particularly the seemingly widespread assumption that women’s perceived risk and perceptions of screening efficacy were the major influences on their intentions to screen.^{53, 97} There were calls for better understanding of a broader range of influences on women’s thinking about breast screening,^{23, 84} and greater acknowledgement of interactions between different influences.^{16, 98} My results reinforced and extended these concerns, highlighting an additional need to extend the wider research focus beyond women to include primary care practitioners, and those people involved in making or influencing breast screening policy and practice. As noted above, there was negligible research on the influences of psychological or ethical factors in relation to the screening views of primary care practitioners, and none at all in relation to the views and decisions of those who exert influence on policy and practice in breast screening. As such, it was not clear whether the views of people in these two groups were susceptible to the same kinds of psychological and ethical factors that influence women. That is, while it was known that primary care practitioners’ referral behaviour was at least partly shaped by their interpretation of a woman’s level of anxiety about breast cancer,⁹⁰ there was much less information about whether or not the screening views of primary care practitioners, or those with influence on breast screening policy and practice, were affected by their own anxieties or worries about breast cancer. Similarly, while it seemed likely that

primary care practitioners and those with influence on policy and practice were, like women, driven by a desire to maximise health outcomes in their patients or in populations, it was not clear what other values might shape their views. For example, there was no empirical knowledge about the extent to which, if at all, the people who make or influence policy regarded the provision of healthcare choice (i.e. about participating in breast screening) as being important in its own right.

The views of primary care practitioners and those who influence breast screening policy and practice are important. As discussed above, the advice and referral practices of primary care practitioners have a large influence on whether or not women attend screening.^{18, 24, 66} The views of those who write or influence screening guidelines and protocols have a significant impact on the screening choices available to women. Breast screening policies themselves, together with the way they are promoted, are likely to have some bearing on women's views on screening.⁸⁴ Given that women's breast screening behaviour is so heavily shaped by the views of primary care practitioners and those with influence on policy and practice, it seemed important to explore the range of factors that influence these groups. The complete lack of research around the views of those with policy and practice influence was identified as a particularly glaring gap in the breast screening literature, and one that I address in the following chapters.

The variable use of terminology found in this study accords with the findings of others, who noted differences in the research use of HBM terms¹⁶ and psychological concepts.⁷⁶ Such differences limit the ability of theoretical models to find results¹⁶ and hamper the value of

review studies. I would encourage researchers to discuss and agree upon terminology, and to publish definitive terms and definitions for common use in this important field.

3.5 Conclusion

Based on this review, I concluded that there were important gaps in the empirical literature, namely research into the factors that shape the views of those who make or influence breast screening policies and practices, including the role of ethical considerations. The next chapters of this thesis address that gap.

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Chapter 4: Aims and Methods

4.1 Background and aims

In the preceding chapters I have presented a history of breast screening with a biomedical focus (**Chapter 1**), and have introduced social and ethical considerations that are relevant to breast screening (**Chapter 2**). I have conducted a literature review into empirical studies on people's views about breast screening, and identified a gap in the empirical literature, namely the views of those who make and influence breast screening policy and practice, and the factors that affect those views (**Chapter 3**). In the remainder of this thesis, I present my empirical research, which addresses this gap, and draw upon my results to make suggestions about how to include ethical considerations in decision making for future breast screening policy and practice. This chapter describes the aims and methods of my empirical work.

The direction of my research was influenced by several factors. Firstly, my experiences as a breast physician, described in the Preface, had given me an interest in exploring the influences of ethical thinking on people's reasoning about breast screening, particularly around the more contentious aspects of breast screening policy and practice. Secondly, I was committed to empirical studies, partly because of an affinity for the empirical turn in bioethics (discussed in more detail below), and partly because I wished to obtain skills and experience in empirical research. I was particularly interested in qualitative research methods, as I felt they were well suited to my areas of interest: ethical reasoning and understanding. My identified gap in the literature concerning the views of those people who make or influence breast screening policies and practices (see **Chapter 3**) motivated me to focus on this group. I therefore determined that my empirical work would concentrate on the role of ethical considerations on the reasoning and opinions of prominent breast screening "experts".

For the purposes of my study I used the term “expert” to mean people with work-related experience in the breast screening arena, who hold, or had previously held, influence on the way that breast screening is carried out. Given my geographical constraints, but also the high level of international prominence amongst local breast screening experts, it made sense to situate my empirical work within the Australian context. Finally, my exposure to the practical use of ethics at the research unit in which I was based, and my interest in empirical ethics stimulated an interest in using the resulting information to draw normative conclusions that could assist with future decision making processes. That is, I was hopeful of being able to guide experts regarding the use of ethical considerations when evaluating, advising, or making decisions in future breast screening policy and practice.

I had three research aims:

1. Identify and analyse the values held by Australian decision makers in relation to breast screening policy and practice.
2. Identify the aspects of the breast screening program that are particularly ethically salient and analyse those in detail.
3. Describe how to incorporate ethical considerations in order to make the best decisions for future breast screening policy and practice.

The remainder of this chapter provides detail on why my chosen methods were selected and a comprehensive description of how I carried out my research. Some of this information is covered in abbreviated versions elsewhere in this thesis, including in the Introductions and Methods sections of published papers.

4.2 Empirical ethics

It is generally accepted that screening programs should be evaluated against public health,² economic, legal, and ethical criteria.^{3,4} The aim of my work was to contribute to the ongoing debate about breast screening by concentrating on the ethical issues. I set out to analyse ethical considerations in breast screening, exploring their role in shaping breast screening policy and practice, and providing practice and normative guidance for future decision making.

There are many conceptual tools that can be used for ethical analysis, including:

- Complete, relatively abstract, ‘ideal’ theories such as Rawl’s theory of justice⁵ and Kantian deontology (for a concise introduction, see⁶), which present what are intended to be universal rules and guidance about right and wrong.
- Non-ideal theories, which are situated in the real, non-ideal world, and aim to be more concrete and immediately practical than ideal theories.^{7,8}
- Mid-level principles such as Beauchamp and Childress’ Four Principles approach⁹ which present a set of action-guiding concepts (beneficence, non-maleficence, autonomy, and justice) that are considered to be important within the context of clinical medicine.
- Casuistry or case-based ethics, which starts with contextual facts and details and builds upon these with intuitive thinking and comparison with other, paradigmatic, cases in order to determine particular rights and wrongs.¹⁰⁻¹²

Each of these approaches has limitations,^{10, 12, 13} whether it be the difficulty of applying idealised theories to a non-ideal world, unintended consequences that were unforeseen even

within non-ideal theories, the lack of guidance about negotiating between conflicting principles, or the lack of satisfactory justification for normative judgments in some case-base reasoning. A fifth approach, and one that I, along with many other writers on screening ethics favour, is to use ethical principles and maxims, but to appropriately refine and apply them through due consideration and analysis of the particular case.^{3, 13} Guided by this strategy, I approached my study with the understanding that ethical theory and empirical research could inform and interact with each other such that existing theory could be used to direct empirical research, and that the data could be used to inform normative conclusions. I aimed to combine the detailed contextual information from empirical work with the normative reasoning underlying philosophical or theoretical ethics, in order to provide new insights into how the world operates and draw normative conclusions about how the world should operate. This approach fits into the relatively newly-described field of empirical ethics, a way of working that is in the early stages of being defined, codified and justified.¹⁴

In this new field, authors have proposed a range of methods for combining theory and empirical work in order to draw normative conclusions.¹⁴ Frith¹⁵ describes an approach that combines empirical evidence with theoretical reasoning, assuming that each can, and should, influence the other in an cyclical manner. In this study, I understood data and theory to be united in a symbiotic relationship such that data collection and analysis could proceed iteratively with reflection on and modification of both the empirical process and my thinking about the ethical concepts that were relevant in the situation.^{15, 16}

In practice, this meant that the categories on which data analysis would focus were clarified and refined as data collection progressed. This was done through an ongoing and iterative

combination of inductive analysis of early empirical data and theoretical reflection. As my analytic categories were developed, they were used to shape the direction of discussion in later interviews. Further data collection contributed to refinement of theory and to further modification of categories, which again influenced data collection. The process was repeated until the data had shaped a particular normative conclusion.

In this way, my research aimed to describe how values influence the views of breast screening experts, and to draw on a combination of empirical data and theoretical analysis to produce normative conclusions about how ethical considerations might best be incorporated into decision making for breast screening policy and practice. It will be clear from the above discussion that my chosen empirical ethics approach required both theoretical and empirical components. The following paragraphs describe my work within each of these domains.

Theoretical approach: principles in screening ethics

Breast screening operates within the dual fields of clinical medicine and public health. Some decisions and policies are made within the context of improving population health, but for many people, particularly women, breast screening appears to be a personal healthcare issue with important ramifications for individual health and wellbeing. The ethical principles relevant to screening therefore need to include those used in both settings. The Four Principles of clinical medicine (beneficence, non-maleficence, autonomy and justice) are well-known and widely used across many different healthcare settings.⁹ As noted in **Chapter 2**, several alternative sets of ethical principles have been suggested for the field of public health, on the grounds that the types of challenges and situations found in public health are substantially different from those in clinical medicine, such that the Four Principles

do not adequately cover the field.¹⁷⁻²⁰ In **Chapter 2** I drew on both medical and public health ethics literatures to review the ethical issues that are either explicitly discussed with regard to breast screening, or can be reasonably inferred to be relevant to an ethical evaluation of breast screening. I used the list of ethical issues identified in **Chapter 2** (and reproduced in **Table 4.1**), worded as principles or maxims, to draft a starting point for my empirical research.

Table 4.1 Ethical considerations relevant to decision making for breast screening policy and practice. (Draft version)

- | |
|---|
| <ul style="list-style-type: none">• Maximise health benefits• Minimise harms• Deliver more benefits than harms• Deliver the most benefit possible within the resources available• Respect autonomy• Maintain transparency, including communicating honestly• Distribute benefits and burdens justly• Uphold reciprocal obligations• Act in solidarity with others |
|---|

SOURCE: Drawn from Chapter 2

During my research I planned to examine the extent to which the empirical situation (in the context of influential Australian experts) matched the largely theoretical literature. That is, I intended to study which, if any, of the ethical concepts in **Table 4.1** influenced decision making for breast screening policy and practice (and if so, how), as well as remain sensitive to any other ethical considerations that appeared to be important.

Empirical approach

I have already reviewed the empirical literature that explores intersection between values and people's views on breast screening (see **Chapter 3**), and described how the lack of research

into the perspectives of breast screening experts represents a gap in the literature. My empirical approach sought to address this gap by gathering data on the views and moral reasoning of experts in breast screening. I used qualitative methods because they were well suited to the collection of rich, detailed data on what it is that people value and how they reason with those values.²¹ Many of these methods were informed by Grounded Theory, particularly as it is practised by Kathy Charmaz,²² but this was not a pure Grounded Theory approach.

4.3 Methods

Participants and sampling

My study population was Australian breast screening experts: people currently or previously working in a breast screening related area who have exerted an influence on breast screening policy and practice. For the purposes of this research, I assumed “influence” to be the fulfilment of one or more of the following criteria in relation to breast screening: writing or presenting for a lay or academic audience, holding a senior position in breast screening provision or administration, holding a professional or consumer representative position within a government or non-government committee, or filling a senior breast screening advocacy role. I was interested in the wide range of views within this population and after obtaining approval from the appropriate ethics committees for my work (see below and **Appendix 9**) I began sampling purposively to achieve maximum variation.²³ I included participants who were publically supportive of breast screening, and participants who had publicly criticised the program. I also reasoned that people’s views might be influenced by factors such as professional role and experience, gender, and local policies and practices, so I

endeavoured to include participants across a wide variety of these characteristics. I sampled across the states and territories of Australia, aiming for a balance of genders and professional roles including: clinical practice (oncology, surgery, breast medicine, radiology, radiation oncology and pathology), non-clinical research (epidemiology and biostatistics), senior administration and senior advocacy. **Table 4.2** provides further detail on the characteristics of participants and those who were asked but did not participate in the study.

Table 4.2 Characteristics of experts²⁴

Participants: 33 (Brackets contain experts who were invited but did not participate: 13)		
Professional role^a	Clinicians ^b 15 (3)	Oncologists 3 (1) Surgeons 4 (0) Breast physicians 1 (2) Radiologists 2 (0) Radiation oncologists 2 (0) Pathologists 3 (0) Clinicians, other 0 (1)
	Non-clinical researchers 14 (3)	Epidemiologists/biostatisticians 9 (1) Researchers, other 5 (1)
	Administrators/managers 6 (2)	Administrators/managers 6 (2)
	Advocacy leaders 6 (7)	Consumers working in advocacy 3 (6) Clinicians/researchers working in advocacy 3 (1)
Public stance on breast screening^c	Supportive 16 (9) Mostly supportive ^d 3 (1) Critical 6 (0) Unknown to researchers 8 (3)	

NOTE: ^aSome experts held more than one professional role. ^bMost clinicians were engaged in research to a greater or lesser extent. ^cI loosely categorised potential interviewees as being “supportive”, “mostly supportive” or “critical” about breast screening based on publicly available commentary. ^d“Mostly supportive” = broadly supportive of breast screening but with selected concerns about one or more elements of the program.

I identified prospective participants from a variety of sources including the lay and academic press, personnel lists from websites of government and non-government advisory and advocacy bodies, and suggestions from colleagues and other participants. I approached experts via email through email addresses that were in the public domain and preserved confidentiality of experts at all times. A copy of the recruitment email and accompanying

information that I sent to experts is provided in **Appendix 10**. These were scrutinised and approved by the appropriate ethics committees (**Appendix 9**).

I contacted 46 experts, and interviewed 33 (72%): 17 males and 16 females who met the inclusion criteria, and who were currently or recently residing across all states and territories. The only location in which I could not identify an expert to interview was the Northern Territory. The thirteen people who did not participate either did not respond (9), did not wish to participate (3) or were unable to participate in the time available (1). I had some initial recruitment difficulties and sought advice from my supervisors as to how to overcome this. Together we developed a variety of strategies. For example, some experts did not respond to my email, although I knew that the address was valid and up to date. In such cases I sent a follow-up email, and generally this was successful. I wondered if some busy experts were uninterested in what might have appeared to be a generic recruitment email and so, with approval from the appropriate ethics committees (see **Appendix 9**), I began to include a targeted comment in my initial email to subsequent experts specifying exactly why I was interested in hearing from them: “I particularly wanted to talk to you because ... [you have published in this area / you are a member of XX committee etc].” I had considerable difficulty recruiting senior consumer advocacy figures. Two leading advocates did not wish to participate and I wondered if they were suspicious of my motivation for researching breast screening. They may have assumed I was sceptical of its value. In subsequent emails, again with ethics committee approval (see **Appendix 9**), I explicitly noted that there were no pre-determined outcomes from my research, and that my goal was to map the range of ideas and understand the reasoning behind them. Several other advocates did not respond to my emails. I wondered if some members of this group might not see themselves as “experts”,

and also considered that there might be a higher turnover of staff in advocacy roles such that at least some advocates may no longer have been working in that role and may not have been contactable at the publically available email address. I persevered with recruitment amongst this group, including, as noted above, targeted comments about why I wanted to speak to each recipient. I was ultimately satisfied that I obtained a sample with sufficient inclusion of a diverse range of professional roles and views about breast screening.

My sampling evolved over the course of the research to ensure that I had adequate representation of the characteristics described above and to follow up on any aspects of the topic that emerged as the data collection and analysis progressed.²² I continued sampling until I was no longer hearing new information and had reached thematic saturation.^{21, 25}

Data collection

I conducted interviews between October 2012 and October 2013. The discussions took place in the participant's workplace, or if that was not convenient, in my office or over the telephone. Each interview lasted between 39 and 105 minutes (average 66 minutes). In keeping with other researchers, I found that face-to-face and telephone interviews were of comparable quality and length²⁶ and telephone interviews were particularly useful in enabling me to speak with experts in distant locations throughout Australia.

Prior to each interview I undertook detailed research about the participant, ensuring that I understood their role and had read any of their published or other public commentary on breast screening. I used a semi-structured interview format, with questions and prompts designed to elicit the expert's views on breast screening and to encourage them to reflect on

underlying values and other influences on their reasoning. I did not use the terminology of values, ethics or morals, neither did I assume that the experts would necessarily be familiar with the theoretical basis or empirical study of these concepts. I began each interview with the consent process (either written or verbal), before progressing to a discussion of my clinical experience as a breast physician and my interest in the different views about breast screening that exist amongst experts. I asked experts about their activities and roles in the breast screening domain, and then loosely followed a series of questions about their views on what was good or bad, and why, within the Australian program. **Appendix 11** contains details of the interview format. Where suitable, the questions were tailored to the individual expert's particular experience and interest. As my data collection and analysis progressed, I adapted the interview questions to elicit particular information that I had identified from previous interviews as being interesting or important.²¹

I was new to interviewing as a research method and so engaged in active training, practice interviewing, coaching, and peer feedback before I commenced data collection. I regularly discussed interview techniques and any problems with my supervisors, seeking ways to improve my skills. For example, although I was often aware of the publicly aired views of the expert, I learnt not to make too many assumptions about their reasoning prior to or during the interview: I might well be wrong in my assumptions, and I might miss out on obtaining their own words and explanations as useful data. I also learnt to introduce the more complex issues with a preliminary description, often prefacing with a comment such as, "You probably know this already but ..." because I discovered that many participants were unaware of the details of aspects of breast screening that were beyond their immediate expertise. Unlike myself, they had not spent the past year or more immersed in all the

different issues and controversies. I initially found it difficult to ask controversial questions, particularly from clinicians. I realised that I had been wanting to reassure clinicians that, as a clinician myself, I understood the pressures and dilemmas inherent in such work, and had not wanted to irritate or offend them by questioning their behaviour or opinions. This meant, however, that I had not necessarily been obtaining a thorough understanding of the clinician's reasoning. After consultation with my supervisors I started to employ useful phrases such as, "I find this question hard to ask, because I see myself as a clinician, but I'm going to ask it anyway..." and I became more confident with asking searching questions. All of the interviews were digitally recorded, professionally transcribed and de-identified.

Data analysis

I began analysis by using the literature and my previous knowledge to draw up a list of topics and concepts that I thought were likely to capture the important elements of experts' comments and which I would use to code the transcripts. I devised shorthand codes for each major point or concept. This list, or index, was refined and re-shaped in response to the data, particularly from the early interviews.²² One version of the index is included in **Appendix 12**, along with other information and documents relevant to my data analysis.

After each interview I wrote a short "Memo 1" which included biographical information about the participant, my initial impressions from our discussion and any new information and ideas that had emerged from the interview (my notes about the writing of Memo 1 are provided in **Appendix 12**). Once each interview transcript was available I read it through several times. I reviewed it for accuracy, crosschecking with my interview recording if necessary, and I deleted any identifying information. Using my index as a guide, I

highlighted phrases and lines within the transcript that represented important concepts and remarks, and identified them with a comment box containing my chosen shorthand. I then collated the identified data from the interview and from Memo 1 into a second memo, titled “Memo 2” (see **Appendix 12**), placing relevant data under template headings that were drawn from the index. I either included highlighted phrases from the transcript or a paraphrased summary depending on whether or not the exact wording seemed important or useful. In either case I included line references so that I could return to the transcript when necessary. The interview did not necessarily provide data that was relevant for each template heading, and in such cases, I simply left parts of the template blank. I used this process to revisit the interview and consider what I had learned from it.

I then distilled versions of Memo 2 into two sets of collated data that I had drafted using the template headings from Memo 2, and which were refined slightly as the research progressed, in response to the empirical findings. The first collation was an excel spreadsheet called the “Chart”, which contained a simple, one or two word summary of the key points from each interview. The Chart was a useful tool for reviewing the data set in its entirety, and for readily comparing and contrasting the findings from each participant. The second collation was a word document titled “Rolling Memo”, which had room for more detailed comments from each interview, together with running commentaries under each heading about the collated data, including notes on any new information and new ideas that were emerging, and a synthesis of how my thinking was evolving. (See **Appendix 12** for excerpts from the Chart and the Rolling Memo.) The ideas behind each of these collations came from the qualitative research literature, including Grounded Theory literature^{22, 25, 27} although they do not

necessarily adhere to any formal descriptions from these literatures, as I have drafted them in my own manner to suit my own analytic purposes as described.²⁸

In summary, from each interview I extracted useful data in the form of: a coded transcript, a set of initial impressions (Memo 1), an individual summary (Memo 2), and contributions to short (Chart) and long (Rolling Memo) collated data sets. At each step I reflected on the findings and used them to create new theories and hypotheses, and refine previous ones. I performed analytic tasks on each interview as soon as the transcript became available (typically two or three weeks), and used the emerging ideas to assist with identification of new participants and to shape the direction and questioning within subsequent interviews. In this way I was moving constantly between theory and data, allowing them to inform each other in an iterative manner. This method of analysis was informed by Charmaz's discussions of the constant comparative method.²²

Throughout this process, particularly after the early interviews, I sought regular guidance and assistance from my supervisors. I talked through my index categories with them at the outset, and again as they were refined in response to my findings. I checked my application of codes by having them independently code two of the earlier transcripts and comparing their results with my own. We regularly discussed emerging concepts and ideas from the data, and how they might feed back into subsequent interviews as well as into new theories. For example, after discussion with my supervisors, I began to ask participants for their comments on suggestions from previous interviewees about how the breast screening program might be improved (e.g. triennial screening instead of biennial; starting at 45 instead of 50 years). I found that this was a good way to introduce and explore contentious topics. On a more

abstract level, I began to ask participants about possible tensions between concepts such as respecting women's autonomy and delivering benefit, or, depending on the expert's interests and the direction of the interview, between more concrete applications of these concepts, such as promoting informed choice and promoting screening participation. These kinds of questions enabled me to test new ideas and theories that were triggered by previous interviews.

Although I had the overall aim of analysing the ethical issues in breast screening and had identified that my work would be empirically informed by the views of breast screening experts (see **Chapter 3**), I did not set out with a detailed outline for the direction of my project or analysis. I planned to allow the important ethical issues to emerge from the data and from my reading of the literature, and to then focus on the topics that appeared likely to be the most rewarding in terms of being new and useful contributions to the debate. My reading of the biomedical literature and public health ethics literature, together with my previous clinical experience, had led me to favour a values-based approach, as noted above. My analysis of the data suggested that experts frequently use values-based concepts when talking about breast screening, and this gave me confidence to proceed with this approach. My first sub-study thus became a detailed analysis of the ways in which experts use values in relation to breast cancer screening (see **Chapter 5**). This was a big project, beginning with my previously drafted principles (see **Table 4.1** above) and altering and expanding this list in response to close reading of my Rolling Memo. I identified the important, frequently discussed values, and worked iteratively between broad thinking across experts and categories to identify patterns, and comprehensive re-visiting of interview transcripts to confirm and validate details. Although I had originally intended to write only about ethical

values, it soon became clear that epistemological values were also highly relevant, so I included these in my published paper.

After writing the first empirical paper, and reflecting further on the literature and the data, it became clear to me that there were two particularly contentious issues in breast cancer screening that I could usefully address: overdiagnosis in breast screening, and communication with breast screening consumers. Overdiagnosis was, and still is, a particularly topical issue in breast cancer screening. The much-anticipated Marmot Report,^{29,30} as it is widely known, was released shortly before I began data collection and was fresh in the minds of many experts. The report included the calculation that for every breast cancer death avoided, three women were overdiagnosed - that is, screening delivered an unnecessary and unhelpful, although technically correct, diagnosis of breast cancer to these three women. The independence and reliability of Marmot and his reporting team gave credence to the concept of significant overdiagnosis harm in breast screening, something that had hitherto been strongly debated but beset by deep methodological disagreement and therefore widely viewed with scepticism. Overdiagnosis was discussed in all of my interviews, having either been raised by the experts or, less commonly, by myself. The interviews provided a large amount of data and many different views about overdiagnosis and I spent considerable time contemplating the ways that ethical thinking intersected with experts' views, and how best to present this. Framing theory offered a good fit for the data and the concepts that I wished to discuss, and I worked on identifying and explaining relationships within and between results and participants.

Communicating with consumers was also a contentious issue. At the time, Australia and the United Kingdom were both in the process of reviewing a government-endorsed breast screening pamphlet that was provided to women³¹ (these revised pamphlets are now available at³² and³³) and there was widespread interest in the type of information and level of detail that should be included. Many experts discussed this topic in the interviews, and differing views emerged strongly. My analysis focused on identifying the ways in which experts' positions were broadly similar or different, and drawing up a simple model to present this to readers. I also worked on uncovering patterns in the data relating to the various ways in which experts reasoned about their views.

The large amount of data that I collected presented a variety of options for further focused analysis. For my final empirical chapter, I decided to use the data to explore socially embedded concepts in the context of breast screening. My reasoning for this was multi-faceted. Firstly, my reading in public health ethics had made me aware of growing academic interest in these kinds of concepts.^{34, 35} For example, publications on reciprocity in public health had been emerging over the last decade, particularly in response to the SARS epidemic in Canada.^{36, 37} There also appeared to be a growing interest in solidarity within public health ethics, including a recent publication from the UK that introduced me to the potential depths of this concept in the context of breast screening.³⁸ Despite all of this, my understanding of socially embedded concepts such as reciprocity and solidarity was somewhat superficial, and I was interested in rectifying this. Secondly, I was concerned by some of the promotional material in current or recent use by breast screening programs (for example³⁹), and by comments that had emerged from my interviews, all apparently stating or describing what women should do in regard to breast screening for reasons that sounded like reciprocity or

solidarity. It was not clear to me that the application of these concepts was appropriate in the context of women's breast screening behaviour. As such, it seemed important that there be a contextual study of the use of socially embedded concepts in breast screening, including a critique of whether or not their current use was in keeping with widespread understanding of what breast screening is about and for. I was excited to undertake this research, although I knew that it would be challenging: unlike the studies into overdiagnosis and consumer communication, I had not had such a clear idea of the importance or even of the boundaries of socially embedded concepts during data collection. I knew that although many experts had talked about them, I had not clearly highlighted this information in any of my memos or summaries. I began, therefore, with intense reading of the literature to gain a deeper understanding of the concepts, then examined my Rolling Memo and multiple, selected transcripts, searching for the relevant data. I soon realised that the data contained more information than I had first expected: as well as applying socially embedded concepts to women's breast screening behaviour, experts talked about associated values in relation to government responsibilities and to the behaviour of themselves and other experts. Iterative reflection on theory and data enabled me to develop useful categories to explain these and other uses of socially embedded concepts in the context of breast screening. I used my reading of the literature to assist and justify my reflections.

Research ethics

I obtained ethics approval for my research from the Cancer Institute of New South Wales Population & Health Services Research Ethics Committee [HREC/12/CIPHS/46] and the University of Sydney Human Research Ethics Committee [#15245]. The committees

specifically approved my original recruitment email and the accompanying material, as well as subsequent amendments. (See documents in **Appendix 9**)

All participants gave individual consent. Those who were interviewed in person were given the consent form to read, and all signed it. Those who were interviewed over the telephone were read the contents of the consent form, and all gave verbal consent. Experts were free to withdraw from the study at any stage but none have withdrawn. All the participants were assured of confidentiality, and because of the relatively small pool of experts within Australia, particular steps were taken to preserve anonymity. For example, when providing information on the professional roles of quoted experts in my published papers I did not provide sub-specialty information, preferring to use more general descriptors such as “clinician” rather than “surgeon” or “oncologist”. I also altered the numerical aliases that I gave to experts for different publications, in order to limit the amount of quoted material that could be identified as arising from any one individual and reduce any chance of recognition. One expert requested that any intentions to publicly quote from their interview be reviewed by them prior to submission for publication. Quotes from this expert have not been used in public.

Follow up

Many participants requested that I keep them informed regarding the progress and findings of the research. In order to comply with this request I have been in individual email correspondence with all participants shortly after publication of each of the research papers included in this thesis. (See **Appendix 13** for an example of this correspondence). Two participants are not contactable via their original email addresses or any others that are in the

public domain. Many participants have replied with very positive responses to my publications and findings.

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Chapter 5: Values in breast cancer screening

5.1 Chapter introduction

This chapter contains the following publication and online supplementary notes:

Parker L, Rychetnik, L, Carter, S. Values in breast cancer screening: an empirical study with Australian experts. *BMJ Open*. 2015;5(5):e006333.

Available at: <http://bmjopen.bmj.com/cgi/content/full/bmjopen-2014-006333?ijkey=4fede9Ou6qJV7y&keytype=ref>

BMJ Open Values in breast cancer screening: an empirical study with Australian experts

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ABSTRACT

Objective: To explore what Australian experts value in breast screening, how these values are conceptualised and prioritised, and how they inform experts' reasoning and judgement about the Australian breast-screening programme.

Design: Qualitative study based on interviews with experts.

Participants: 33 experts, including clinicians, programme managers, policymakers, advocates and researchers selected for their recognisable influence in the Australian breast-screening setting.

Setting: Australian breast-screening policy, practice and research settings.

Results: Experts expressed 2 types of values: ethical values (about what was good, important or right) and epistemological values (about how evidence should be created and used). Ethical values included delivering benefit, avoiding harm, promoting autonomy, fairness, cost effectiveness, accountability, professionalism and transparency. Epistemological values informed experts' arguments about prioritising and evaluating evidence methodology, source population and professional interests. Some values were conceptualised differently by experts: for example, delivering benefit could mean reducing breast cancer mortality, reducing all-cause mortality, reducing mortality in younger women, reducing need for aggressive treatment, and/or reassuring women they were cancer free. When values came into conflict, experts prioritised them differently: for example, when experts perceived a conflict between delivering benefits and promoting autonomy, there were differences in which value was prioritised. We explain the complexity of the relationship between held values and experts' overall views on breast cancer screening.

Conclusions: Experts' positions in breast screening are influenced by evidence and a wide range of ethical and epistemological values. We conclude that discussions about values should be a regular part of breast-screening review in order to build understanding between those who hold different positions, and provide a mechanism for responding to these differences.

INTRODUCTION

Mammographic breast screening was first performed in the mid-20th century and became

Strengths and limitations of this study

- This is the first application of empirical ethics to breast-screening policy and practice outside of consumer studies.
- The study has a wide reach, using data from a broad selection of key players in breast screening and covering all important stakeholder groups across the country.
- The rich data set and detailed analysis provides a comprehensive picture of how values guide thinking and influence experts' opinions on mammographic screening.
- Experts in other jurisdictions, with different organisational structures and different societal values, may express different views. However, since the Australian programme shares much in terms of rationale, purpose and implementation with counterpart programmes in the UK and many European countries, it seems likely that our results will be at least partially transferable to these contexts.
- There may have been differences between experts who agreed to participate and those who did not. However, we purposely interviewed experts from a range of backgrounds and public opinions about breast cancer screening.

widespread in the 1980s. Public and professional debate about mammography screening began immediately,¹⁻³ and intensified after publication of controversial meta-analyses of breast screening randomised controlled trials that suggested lower benefits than originally calculated⁴⁻⁶ and significant overdiagnosis.⁷⁻⁹ (Throughout this paper, we use overdiagnosis to mean: diagnosis of non-progressive or slowly progressive breast cancer through screening, a diagnosis that does not produce a net benefit for the women diagnosed. We use the term overtreatment to mean the treatment of overdiagnosed cancers, treatment which is, by definition, unnecessary¹⁰⁻¹²). It was widely hoped¹³ that the recently updated review of the evidence by Marmot *et al*¹⁴ would put an end to the controversy, but disagreements between experts about breast screening persist, particularly around the amount of benefit and the risk of overdiagnosis.¹⁵ Such disagreements can be a challenge



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for policy and practice, particularly if they persist and seem intractable. Relatively little is known about how breast screening experts develop different interpretations of the evidence on the benefits and harms of breast cancer screening. There have been a number of suggestions. Some attribute the differences to variable epidemiological understanding of potential biases.^{12 16 17} Others acknowledge the possible effect of professional bias or vested interests,^{6 12 17-19} or differing historically based assumptions about the biology or inevitability of cancer growth.²⁰ While these are all potentially relevant, it is likely that there are also deeper differences underlying the variation in experts' positions: that is, these experts may have different ideas about what is important and what matters with regard to breast screening^{21 22} and/or the evaluation of evidence.⁶ Well-meaning, thoughtful and epidemiologically competent experts may hold a range of views and ideas about breast cancer screening owing to differences in how they prioritise certain values or principles.

Values are integral to public health programme planning and are emphasised in the aims of many national breast-screening programmes including those of the UK,²³ Australia²⁴ and many European countries,²⁵ which refer to concepts such as delivering benefit, avoiding harm, accountability and recently, transparency and respect for autonomy. Many authors also see values as being important in the creation and interpretation of evidence.^{26 27} Our commitment to different values may be expressed overtly, via debates and discussions about these values; but debates around such issues are rare in the literature on breast screening. This sidesteps important conversations about what is important and gives limited acknowledgement to the role of these values in determining breast-screening policy and practice decisions.

The idea that values are important in healthcare is not new. There has been considerable interest in paying attention to: patients' values in clinical practice²⁸ and health technology assessment;²⁹⁻³¹ citizens' values in healthcare policy;^{32 33} and health practitioners' values in clinical practice.^{34 35} This way of looking at healthcare not only assumes the importance of values in healthcare,³⁶ but also accepts a plurality of values among different stakeholders, and emphasises the need to explore and work through values' differences during healthcare decision-making.³⁵ With these ideas in mind, we aimed to investigate experts' values in breast screening, with a view to identifying new means by which persistent disagreements in this field might be understood or mitigated.

This study is part of a larger Australian National Health and Medical Research Council-funded project examining ethics and evidence in cancer screening. In this paper, we report on one component of a substudy focused on ethics and evidence in screening for breast cancer. Our aim in this paper is to empirically examine the values or principles that Australian experts employ when evaluating the Australian breast cancer screening programme.³⁷ We reasoned that by developing a clearer

understanding of the values employed by these experts, we could move towards a better understanding of the debate about this changing and sometimes difficult topic. We focused on experts because (1) they are well-informed relative to the general population of citizens, policymakers or researchers; (2) disagreement between experts has been a central feature of breast screening, so mapping experts' values should assist in understanding this disagreement and (3) these experts have influenced breast-screening policy and practice, both directly through decision-making bodies, and indirectly by influencing consumer groups and other policymakers.

Our research questions were:

- ▶ What are the values expressed in the talk of Australian experts about breast screening in Australia?
- ▶ What are the implications for policy and practice of experts holding particular values?

METHOD

Methodology

This study employed a qualitative methodology, with sampling, data collection and analysis strategies designed to best answer our research questions.³⁸ We used open qualitative methods because there was little pre-existing knowledge about the topic and because we sought to access the values of participants on their own terms. We were motivated by our commitment to empirical bioethics, in particular to the view that practice and theory must exist in a symbiotic relationship, where each has the potential to alter the other.^{39 40} We undertook this study in that spirit, expecting that existing ethical theory would inform our analysis, but also that our data and analysis could make a useful contribution to ethical theorising in the area of breast screening. We have considerable experience and knowledge of grounded theory methodology, which informed our study design,^{41 42} but this was not strictly a 'grounded theory study'.^{43 44}

Participants and sampling

We selected participants from the population of 'influential experts', individuals who had engaged in frequent media commentary, publications, senior administration or management, advice to government or professional committees, or senior advocacy on breast screening. We sampled purposively for maximum variation⁴⁵ of ideas, deliberately inviting participants with strongly divergent opinions (table 1). We also reasoned that perspectives may be associated with professional responsibilities and experiences, so contacted participants with a range of professional roles.

We identified potential interviewees by scanning academic and popular media publications on breast screening, and personnel lists on websites of organisations involved in breast screening. We also followed up on suggestions from colleagues and previously interviewed experts. As experts, all participants were able to be contacted via information in the public domain.

**Table 1** Characteristics of experts**Participants 33 (brackets contain number of experts who were invited but did not participate; 13)**

Professional role*	
Clinicians† 15 (3)	Oncologists 3 (1) Surgeons 4 (0) Breast physicians 1 (2) Radiologists 2 (0) Radiation oncologists 2 (0) Pathologists 3 (0) Not otherwise specified 0 (1)
Non-clinical researchers 14 (3)	Epidemiologists/biostatisticians 9 (1) Not otherwise specified [NOS] 5 (1)
Administrators/managers	Administrators/ managers 6 (2)
Advocacy leaders 6 (7)	Consumers working in advocacy 3 (6) Clinicians/researchers working in advocacy 3 (1)
Public stance on breast screening‡	
Supportive 16 (9)	
Mostly supportive§ 3 (1)	
Critical 6 (0)	
Unknown to researchers 8 (3)	

*Note that some experts held more than one professional role.

†Most clinicians engaged in research to a greater or lesser extent.

‡We loosely categorised potential interviewees as being 'supportive', 'mostly supportive' or 'critical' about breast screening based on publicly available commentary.

§Broadly supportive of breast screening but with selected concerns about one or more elements of the programme.

We approached 46 experts via email, and interviewed 33 (17 male and 16 female). Thirteen people either refused (3), or were unable to participate (1), or did not respond to emails (9). We had a particularly low response rate from volunteers who were on public record as holding senior roles in consumer advocacy organisations. This may have been due to a higher turnover of people in these positions than in other professional roles: they may no longer have been working as advocates when we sent our email. Our sampling evolved as analysis progressed, ensuring that we had enough representation of positions and roles to give us confidence in our findings.⁴¹ We continued to sample until we reached thematic saturation.³⁸

Data collection

LP conducted semistructured interviews face to face in the expert's or LP's workplace, or by telephone, if unavailable to meet in person, from October 2012 to October 2013. Interviews lasted 39–105 min (average 66 min). In keeping with reports from the literature, we found that face-to-face and telephone interviews were of comparable quality and length.⁴⁶ Utilising telephone interviews enabled us to interview experts across the country.

Interviews were designed to elicit experts' views and opinions on breast screening in Australia. LP described her interest in the topic as a medical practitioner undertaking doctoral studies in cancer-screening ethics. She noted aloud that there was an obvious range of opinions among experts despite, and often about, the large evidence base, and suggested that she was interested in exploring this further. The aim of the interviews was to ensure that participants could speak freely without

experiencing any judgement regarding their views. We did not ask direct questions about abstract values or principles, instead we asked about interviewees' experience of the breast-screening programme and their views on what was good or bad and why (see online supplementary appendix). Interviews were digitally recorded, transcribed by a professional service, and de-identified.

Analysis

Analysis focused on developing a set of categories that captured the most important values in experts' talk. Our goal was not to develop a theory, but to identify mid-range ethical concepts being used by participants, and understand what those concepts meant in use. Interviews were read repeatedly and coded in detail to capture values-in-use. From codes, more abstract categories were developed; these evolved iteratively as the data collection and analysis progressed. LP wrote analytic memos for discussion, and shared these with other authors for discussion. Coding, categorisation and memo writing were closely informed by Charmaz's iteration of the constant comparative method.⁴¹

All participants gave individual written or verbal consent, were assured of confidentiality, and were free to withdraw from the study at any stage.

RESULTS

Experts disagreed as to whether, or to what degree, values influenced their thinking

Although all experts discussed value-laden concepts in relation to breast screening, they varied in how much



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they considered values to be important in shaping their opinions. Many experts suggested that values influenced their thinking, volunteering that “ideology” (#15 epidemiologist), “values” (#17 researcher, not otherwise specified (NOS)) or “judgements” (#13 consumer advocate), as well as evidence, influenced how they and others formed opinions about breast screening. Others denied the influence of values, contrasting value-based reasoning (characterised by use of “intuition, judgement, political trickery, [and attending to] those with the loudest voice” (#29 epidemiologist) against scientific reasoning (in which, ‘the figures cannot lie’ #21 epidemiologist). For these experts, using values meant being biased or unscientific, and as such, should be avoided: “I’m a scientist, I look at the available evidence and I try and evaluate that impartially” (#9 oncologist).

A single expert presented a unique argument against using values when reasoning about breast screening. Using values, they argued, required deep, philosophical reflection. They saw themselves as a person of action rather than reflection, which meant values thinking was

not relevant to them. This view suggested that values thinking was only for philosophers or academics, not for practitioners, and implied that practitioners could maintain a value-free position.

Experts invoked ethical and epistemological values in their talk

At the most abstract level, experts’ value-talk about breast screening could be categorised into two main groups: ethical and epistemological (table 2). Ethical values related to ideas about the right thing to do:

There [is] disagreement amongst experts about what we should do. Even if you had a room full of people agreeing on the evidence, you would still get different ideas about screening. I think it’s values ... that is responsible for those differences. (#17 researcher NOS)

Epistemological values related to preferred sources of knowledge, including the nature of evidence-based reasoning:

Table 2 Experts’ views on values that are important in breast cancer screening

Ethical values	The range of meanings-in-use of this value* (<i>common conceptions of values are in italics</i>)
Delivering benefits†	Breast cancer-related benefits (mortality: <i>reducing population breast cancer mortality</i> ; reducing breast cancer mortality in non-elderly women. Morbidity: <i>enabling less aggressive treatments; providing reassurance; reducing population burden of disease—incidence of total/advanced breast cancer</i>) Non-breast cancer-related benefits (reducing all-cause mortality; improving health for communities with the poorest health outcomes)
Avoiding harms†	<i>Low overdiagnosis rate; low false positive rate; minimal overtreatment</i> ; minimal pain and inconvenience; low false negative rate (false reassurance)
Respecting autonomy†	<i>Providing information; facilitating informed choice</i> ; providing screening to women in the target age range; providing screening upon request for older women beyond the target age; maximising breast screening participation so that women will have the knowledge to make decisions about their future
Equity	<i>Providing equal access to breast screening</i> ; contributing to equal health outcomes for all
Economic efficiency	Cost effective relative to other health interventions; minimising inefficiencies
Accountability	Regular audit and evaluation
Professionalism	Performing well at required tasks of job; providing individualised and patient-centred care to consumers
Fair process for policy decision-making	<i>Including all stakeholders</i> ; excluding those with possible vested interests; asking public opinion on worthiness of breast screening; asking public opinion about breast-screening policy if the scientific evidence is uncertain
Transparency	Ensuring that underlying values that guide breast-screening policy are clear to consumers
Epistemological values	The range of meanings-in-use of this value
Evidence-based knowledge†	Randomised controlled trial evidence; all relevant scientific studies; scientific studies that have been rigorously analysed for bias; preference for local and recent service studies; must include evidence about harms; avoiding modelling studies; including modelling studies; evidence as evaluated by expert methodologists; evidence as evaluated by impartial scientists without vested interests; including studies of ‘uninformed’ consumer opinions; excluding studies of ‘uninformed’ consumer opinions
Other knowledge sources	Clinical experience; logical reasoning; personal stories; government endorsement; include those with extreme opinions; assume truth is in the middle

*Some experts may use more than one meaning simultaneously.

†Most commonly discussed values.



What ... people do with the same evidence and the same statistics is, in the main part, ideologically driven...I don't think that anything is value-free—[that] any scientific statement is particularly value-free. (#15 epidemiologist)

As shown in [table 2](#), the range of ethical values discussed by experts related to familiar concepts from the literature, including the influential Four Principles⁴⁷ of clinical medicine (delivering benefit, avoiding harm, respecting autonomy, supporting justice), as well as principles more commonly endorsed in public health practice or public health ethics (economic efficiency, accountability and fair and/or transparent decision-making processes). Experts also valued professionalism.

A range of epistemological values was also expressed ([table 2](#)), with experts describing ways of thinking about knowledge, including views on constructing or reviewing the scientific evidence base and uses of non-evidence-based knowledge.⁴⁸

Experts had different interpretations of value-related concepts

Although experts' value talk reflected familiar ethical and epistemological concerns, our central finding is this: there was substantial variation in the way experts conceived of each value. This is consistent with the literature, which acknowledges and discusses such distinctions and complexities.³⁵ The range of ways that experts conceive of each value is shown in [table 2](#). The most commonly discussed values were also the most variably constructed: we discuss this in detail below.

Delivering benefits

Experts' conceptions of delivering benefit in breast screening fell into two main categories: breast cancer-specific and non-breast cancer-specific outcomes. All experts talked about breast cancer-specific benefits, including reduced population breast cancer mortality and morbidity. Morbidity was mostly discussed in terms of enabling less aggressive treatment and reducing population breast cancer burden. Two experts (both consumer advocates) also included breast cancer-related reassurance:

Some of that benefit might be just peace of mind, the fact that you don't, as far as they can tell, have breast cancer. (#24 consumer advocate)

Most experts suggested that breast screening delivered modest to substantial population mortality benefits. Many also saw the breast cancer morbidity benefits of screening as substantial, but others saw them as being absent. Participants' conception of morbidity appeared to inform their perception of the presence or absence of this benefit. When participants said, 'screening offers morbidity benefits' they usually meant 'screening reduces the treatment needed, or provides reassurance'. When participants said, 'screening does not offer morbidity benefit' they usually meant, 'screening does not decrease

the burden of breast cancer illness in populations' (generally because of the impact of overdiagnosis).

A small group of experts argued that breast screening did not deliver benefits. When they argued this, they used a broader, non-breast cancer-specific concept of benefits, and meant either that screening did not reduce all-cause mortality, or that screening did not assist the communities with the poorest health outcomes. These experts were concerned that the high cost and attention paid to breast screening meant that other, possibly more worthy, public health programmes were not implemented, meaning that the important public health benefit of improving health outcomes for the most needy was not realised.

Avoiding harms

Experts' described (avoiding) harm in a variety of ways ([table 2](#)), with two main patterns and a third minor pattern emerging. One group of experts, comprised mostly of researchers, conceived of harm as being mainly about overdiagnosis. A second group, mostly clinicians, saw significant harms in false-positive diagnoses and/or overtreatment. Not all researchers or clinicians expressed a clear conception of harm, and of those that did, not all described it along these lines. However, these two major patterns were associated with particular professional roles, suggesting some influence of availability bias.⁴⁹ Researchers whose work involved calculating overdiagnosis in populations tended to conceptualise harm as overdiagnosis. By contrast, clinicians working with identifiable patients receiving false-positive results and negotiating between appropriate treatment and overtreatment, tended to see harm in these terms. A third, less widely expressed view about harms concentrated on women's experience of the screening process. This view was held by all three consumer advocates and one researcher, who described harm in terms of minor physical discomfort and inconvenience, and denied that overdiagnosis or false positives caused harm:

Women aren't being harmed by breast screening and society isn't being harmed by breast screening. It's ... a little mindset that has developed. (#13 consumer advocate)

As with benefits, we saw correlations between experts' concepts of harm and ideas about levels of harm. Those who viewed harm as overdiagnosis perceived harms as more extensive than those who viewed harm as false positives, overtreatment, or unpleasant experiences.

Respecting autonomy

Experts expressed differing versions of what respecting autonomy means in breast screening. The dominant view was that respecting autonomy is about providing comprehensive information to women who are offered breast screening. A less common view, described by a smaller number of experts, including all three consumer



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advocates, placed respecting autonomy as being about the provision and promotion of breast screening, as this enabled women to “find out whether you have [a cancer] or not” (#24 consumer advocate) early enough to enable less aggressive treatments. For these experts, information was less central to autonomy than the option/encouragement to screen. They advocated limiting information in order to avoid scaring women away.

Epistemological values

Most experts viewed the scientific evidence as the most important source of knowledge about breast cancer screening. There was a wide spread of ideas, however, about what constitutes ‘good’ scientific evidence (table 2), and this spread was evident across the subgroup of epidemiologists and biostatisticians. For example, some epidemiologists said it was important to consider all studies, others preferred only top-quality studies, some prioritised recent, local service studies, and there were differing opinions about mathematical models. Several experts emphasised their own studies when discussing examples of evidence that they used and trusted.

A smaller number of experts described their lack of understanding of the scientific evidence on breast screening. Some explained that they still viewed this evidence as important and relied on the interpretation of trusted colleagues or opinion leaders. Others, including two who openly stated that they did not trust the scientific evidence, described additional or different sources of knowledge (table 2) including: “intuitive interpretation based on what has changed in breast screening over 30 years ... [and] common sense” (#23 surgeon). We did not find a clear pattern linking experts’ epistemological values and their overall opinion about breast screening, and could not predict, from expressed epistemological values, whether experts would be supportive or critical of breast screening.

Experts’ awareness about different interpretations

Some experts were aware of variations in how values were conceived, occasionally referring to an alternative conception to their own, mainly in order to reject it. Discussion of such differences was not common, however, most experts expressed values implicitly rather than explicitly, and did not explore alternative meanings of the values they were using. This opens the possibility that experts may sometimes be speaking at cross-purposes about what is important in breast screening, despite using similar terminology.

Conflicting values

Many experts described a perceived conflict between one or more values in the breast-screening context. They saw certain values as being in tension with each other, such that respecting one value would necessarily entail sacrificing the other. Most experts who discussed conflicting values described tensions between respecting autonomy and delivering benefit. These experts equated respecting

autonomy with providing information, and felt that providing information to consumers might reduce participation rates and, therefore, lower breast cancer mortality and morbidity benefits of screening. Some experts simply described a spectrum of positions that one could take regarding these conflicting values, such as ‘the continuum between individual autonomy and public health’ (#17 researcher NOS). Others openly favoured one value over another, with implications for practice. Those who prioritised delivering benefits, for example, preferred to limit breast-screening information in order to avoid frightening women away. Those who prioritised autonomy were in favour of providing more comprehensive information and encouraging informed choice.

A smaller number of experts discussed conflicting values in terms of avoiding harms and delivering benefits. Their view about the relative importance of these two values had practical implications for whether or not they supported breast screening: those who prioritised avoiding harm were less likely to support screening than those who prioritised delivering benefits. Experts’ conceptions of harm were also important, however, and box 1 describes several examples of ways in which the combination of experts’ conception and prioritisation of ‘avoiding harm’ might affect their level of support for breast screening.

As reported, experts rarely discussed alternative conceptions of a particular value different to their own. By contrast, experts frequently referred to alternative ways other experts might *prioritise* values. Several experts agreed that an important step towards resolving conflict in breast screening was to seek consensus on which values to prioritise.

DISCUSSION

We have shown that experts’ positions in breast screening are influenced by more than just the evidence⁵⁰; they are also influenced by a wide range of ethical and epistemological values. We have demonstrated considerable variation in how experts conceive of individual values, and how they prioritise certain values over others. These differences, together with a lack of knowledge about how one might, or whether one should, engage in explicit values-based discussions, suggests a vast potential for fundamental disagreement about screening policies and programmes.

Disagreements in breast screening have persisted despite multiple meta-analyses of the breast-screening evidence, including the recent Independent Review led by Marmot.¹⁴ This review made a vital contribution, providing a highly regarded consensus on quantification of mortality reduction and overdiagnosis. Its publication was, however, immediately followed by disputes about both the conclusions and their implications for policy and practice.¹⁵ We noted earlier that differences of opinion of this sort are often attributed to the correctness or incorrectness of evidence interpretations,^{12 16 17}

**Box 1** Conception of values and prioritisation of values influences experts' opinions on breast screening

The following three case study examples from the data illustrate how experts' conception and prioritisation of 'avoiding harm' can influence their opinions on breast screening.

Expert A (#21 epidemiologist) saw breast-screening harm in terms of overdiagnosis and considered these harms to be substantial. This expert saw both avoiding harms and delivering benefits as being important, but because harms were, in their view, so large, was not supportive of the breast-screening programme.

Expert B (#10 epidemiologist) saw breast-screening harms as being limited to those inconveniences that women experienced as a result of attending screening services: thus, they were seen as very minor. Thus, although this expert believed strongly that avoiding harms should take priority over delivering benefits in the context of public health programmes in general, the harms from breast screening were, in their view, so negligible they were strongly supportive of breast screening.

Expert C (#9 oncologist) saw breast-screening harm in terms of overdiagnosis. This expert was uncertain as to the level of overdiagnosis harm: "you don't know how much to worry about that" but assumed it was, "probably lower than in some of the other screening programs." They thought delivering benefits should take priority over avoiding harms: "[Some] professionals may put a higher weight and value on 'first do no harm'. It's a point of view. It's not my point of view." Their overall opinion was, like Expert B but via a very different route, highly supportive of breast screening.

but our findings suggest that evidence interpretations may also be related to variations in epistemological values. Other authors attribute disagreements to vested interests.^{6 12 17–19} Although we did not explore experts' financial or commercial interests in this study, many participants had direct clinical and/or research interests in breast screening. Their familiarity with and trust in their own work may have led them to ignore or discount evidence that presented an alternative view. More significantly, our study suggests another, potentially more subtle set of reasons to explain differing opinions: experts may hold quite different values, or different versions of the same values. Even epidemiologically competent and non-conflicted experts may disagree about breast cancer screening because of deep value commitments. They may be working from very different understandings of what is good or bad about breast screening, what its goals should be, and what matters.

Strengths and limitations

The strengths of this study are its empirical nature and the completeness of its reach. This is, to the best of our knowledge, the first empirical ethics study with breast-screening policymakers and practitioners. We were able to interview a wide selection of key players in breast screening in Australia, and so could provide a comprehensive picture of experts' values and reasoning. Possible limitations include the focus on Australia, as experts from

other jurisdictions may hold different values. However, since the Australian programme shares much in terms of rationale, purpose and implementation with counterpart programmes in the UK and many European countries, it seems likely that our results will be at least partially transferable. Note, that we were not seeking to demonstrate the prevalence of particular values (which would require a survey in a population-based sample), rather, we aimed to capture the range and variety of values. By continuing our sampling and analysis until we reached thematic saturation we are confident that we have achieved this aim.³⁸ Finally, it is possible that experts who agreed to take part were somehow different from those who did not, however, we sought to minimise such potential bias by ensuring that we interviewed experts from a range of backgrounds and professed opinions about screening.

Implications for practice, policy and research

Our findings have strong implications for practice and policy, as both the way experts conceive of values, and the types of values they prioritise, directly influence the positions they take regarding breast screening. The current situation where values are rarely explicitly considered or discussed is not ideal. We do not presume that all experts should adhere to one set of 'correct' public health values, or even that such a thing exists. Rather we argue for a closer, more explicit examination of the values underpinning breast-screening service provision and policy by individual experts, in expert decision-making bodies, and in the public domain.^{51 52} Our findings highlight several issues suitable for specific examination by breast-screening decision-makers, the public and researchers (box 2).

If stakeholders are able to be more transparent about values, this may enable people with seemingly divergent positions to recognise points of agreement, or at least improve their understanding of why others think the way they do, helping to build bridges between opposing viewpoints. It should also assist with the justification of breast-screening policy, and wider debate about concordance or discordance between the values of influential experts and the considered judgements of the community.^{39 53} Empirical investigation of citizens' values regarding breast screening was beyond the scope of this project, but is an important issue for future research. Broad engagement regarding what is important to experts and citizens (eg, by using a citizen's jury model³²) could support the development of an explicit framework of values to guide future decision-making on breast screening.⁵⁴ This would not be straightforward: the plurality and apparent incommensurability of values in communities is well recognised, such that it may be best not to expect or force a consensus, but rather to focus on the fairness of the decision-making process.⁵⁵ Regardless, Weed⁵⁶ reminds us that more engagement with and knowledge about ethics and values has a tendency to lead to more ethically appropriate decisions, and that this is a worthy aim in provision of healthcare and public health services.



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Box 2 Examples of value-related topics that warrant further research and public debate

- ▶ *Plurality of experience influencing values:* Our study suggested a likely impact of availability bias on some experts' conceptions of values. Experts are likely to understand concepts such as harm, benefit and autonomy differently depending on what they encounter day to day (eg, population-level data, or individual women experiencing disease or the consequences of screening). We suggest that conversations and attempted definitions about values in breast screening should endeavour to include a plurality of professional roles and experiences in order to cover the likely range of conceptions of relevant values.
- ▶ *Focus of population health programmes:* Some participants in our study concentrated on the impact of breast screening on all-cause mortality or on the health of vulnerable populations, expressing concern that, in their view, breast screening had minimal impact on these, and that the programme was associated with substantial opportunity costs. This raises questions about the aim or focus of population health programmes, and indicates that there may be differences between people's opinions about exactly where that focus should lie. It would be useful to elucidate the range of relevant values on this issue.
- ▶ *Breast cancer consumers' view of screening:* Consumer advocates in this study presented a very particular view of breast screening. They emphasised morbidity benefits including reassurance; tended to suggest that harms were minimal; and argued that the best way to respect women's autonomy was to provide them with, and promote, screening services, as this allowed them to access information about their personal breast cancer risk. It seems possible that these ways of thinking about screening may risk generating 'too much medicine'¹⁰ for women. We were only able to interview three consumer advocates, and as such our findings may not be indicative of the entire range of opinion in the breast cancer consumer movement. However, the experts that we spoke to were in senior consumer advocacy roles, and expressed remarkably consistent positions on each of these three important values. Further research is needed to explore the range of values held by consumer advocates. If our findings are transferable to breast cancer consumer advocacy more generally, it seems possible that these values may promote and protect screening activity, but provide little avenue for adjustment or improvement in line with new evidence and technologies.
- ▶ *Professional ethics education:* Opportunities to participate in training in thinking explicitly about ethics and values may assist experts in the difficult task of decision-making.⁵¹ Thinking and talking about values is not easy, not least because—as we have shown—the same terminology can be used to communicate very different meanings. Explicit training has the potential to increase the robustness and contextualisation of reasoning about breast screening, both by individuals and in decision-making bodies.^{39 53}

Engagement with values in breast screening—or any other area of health intervention—cannot be a once-only activity, as values change over time in expert and lay communities. For example, since organised breast screening began, consumer leaflets have become increasingly detailed and information rich, reflecting the generally increasing value given to promoting the autonomy of healthcare consumers.⁵⁷ Changes in epistemological

values have also occurred, including the introduction of evidence-based medicine,⁵⁸ changed thinking about study quality,⁵⁹ and the growing attention to impartial reviews by independent experts.^{13 14} Growing evidence about overdiagnosis has changed the way we think about and prioritise the value of avoiding harm. Research about values, and processes to incorporate values in policy setting and decision-making, will need to evolve and continue to reflect this ongoing change. Debates around ethical and epistemological values should sit alongside the regular discussions of evidence, as part of ongoing processes for planning the future of breast screening.

Contributors LP initiated and performed the study, and prepared the first and subsequent drafts of the paper. LR and SC assisted with study planning and data analysis, trained and supported LP in data collection and analysis methods, and made substantial contributions to draft revisions throughout. LP is the guarantor.

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APPENDIX

Sample interview questions (note: this list is provided as a guide only; the questions were modified to suit the experience and perspective of the interviewee)

- Can you tell me the story of your involvement in breast cancer screening, starting from when you first got involved and taking us up to the present?
- Thinking back to the late 1980s and early 1990s, when breast screening was being introduced in Australia, did you have any particular views on it then? Have they changed?
 - *Prompt for current views:* I know you have written about breast cancer screening in... Can you expand on that?
- Would you like to see any changes to the current program?
 - *Prompt:* What would your ideal program be?
- What would it take to make such changes happen?
 - *Prompt:* who do you think should be making decisions about breast screening and what should that process look like?
- There are many different ideas about breast cancer screening. Can you comment on these?
 - *Prompt:* There are some who hold very extreme views about breast cancer screening. How do you respond to these ideas? What do you think drives those views?
- *(If the topic hasn't yet surfaced)* Recent studies suggest that some invasive cancers found at screening would never have come to clinical attention in that person's lifetime; for example, Marmot and colleagues suggest that for every 1 life saved by breast screening there are 3 invasive cancers overdiagnosed. What are your thoughts on this issue?
 - *Prompts:* What level of overdiagnosis do you work with (eg is it – non-existent; exists but not a problem; a problem but not as great as the Marmot report suggests etc)? Should screening programs take responsibility for reducing overdiagnosis or should it be addressed elsewhere, for example, at the treatment stage?
- Obviously you can't read the future, but given your expertise and experience, what do you think will happen within the Australian breast screening program?

Chapter 6: Overdiagnosis in breast cancer screening

6.1 Chapter introduction

This chapter contains the following publication and additional online files:

Parker LM, Rychetnik L, Carter S. Framing overdiagnosis in breast screening: a qualitative study with Australian experts. *BMC Cancer*. 2015;15(1):606.

Available at: <http://www.biomedcentral.com/1471-2407/15/606>

RESEARCH ARTICLE

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Framing overdiagnosis in breast screening: a qualitative study with Australian experts



Lisa M. Parker^{1*}, Lucie Rychetnik² and Stacy Carter¹

Abstract

Background: The purpose of this study was to identify how the topic of overdiagnosis in breast cancer screening is framed by experts and to clarify differences and similarities within these frames in terms of problems, causes, values and solutions.

Methods: We used a qualitative methodology using interviews with breast screening experts across Australia and applying framing theory to map and analyse their views about overdiagnosis. We interviewed 33 breast screening experts who influence the public and/or policy makers via one or more of: public or academic commentary; senior service management; government advisory bodies; professional committees; non-government/consumer organisations. Experts were currently or previously working in breast screening in a variety of roles including clinical practice, research, service provision and policy, consumer representation and advocacy.

Results: Each expert used one or more of six frames to conceptualise overdiagnosis in breast screening. Frames are described as: Overdiagnosis is harming women; Stop squabbling in public; Don't hide the problem from women; We need to know the overdiagnosis rate; Balancing harms and benefits is a personal matter; and The problem is overtreatment. Each frame contains a different but internally coherent account of what the problem is, the causes and solutions, and a moral evaluation. Some of the frames are at least partly commensurable with each other; others are strongly incommensurable.

Conclusions: Experts have very different ways of framing overdiagnosis in breast screening. This variation may contribute to the ongoing controversy in this topic. The concept of experts using different frames when thinking and talking about overdiagnosis might be a useful tool for those who are trying to negotiate the complexity of expert disagreement in order to participate in decisions about screening.

Background

Overdiagnosis in breast screening has become a highly contentious issue and source of strong disagreement amongst experts. In this paper we use the term “overdiagnosis” to mean the diagnosis through mammographic screening of an asymptomatic breast condition that is non-progressive or so slowly progressive that it would not otherwise have come to the patient's attention in her lifetime, and where this diagnosis provides no net benefit to the patient [1]. The possibility of overdiagnosis in breast screening was acknowledged from its early days of use. The idea that breast screening might lead to the

detection of lesions that are “morphologically malignant but clinically benign” was raised as early as the 1970s ([2], p490). Later it was also recognised that mammographic screening would uncover a significant number of in-situ cancers, at least some of which “might not have entered an invasive phase during their lifetime” ([3], p14) and would likely fall into the category of overdiagnosis. Despite this, there was limited controversy about overdiagnosis when breast screening programs were being introduced in many Western countries during the 1980s and 1990s. This may have been partly because of poor outcomes from treatment of symptomatic breast cancers and the evidence-based promise of a 30 % reduction in population breast cancer mortality.

Since that time, however, the evidence-based estimates of the mortality benefit from breast screening have been revised and reduced [4, 5]. In addition, improvements in

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breast cancer treatment are likely to have further reduced the potential impact of screening in the modern Western setting [5, 6]. These developments have fostered a growing interest amongst breast screening experts about the significance of overdiagnosis, which is now a topic of major international concern [7–9].

Researchers and clinicians present many different views about overdiagnosis, and focus on different problems and solutions, including: preventing overdiagnosis harm [10]; communicating with women about overdiagnosis [11–13]; and quantification of overdiagnosis [14–16]. There are also big differences of opinion within these topics. Understanding how and why experts form their opinions about this complex issue, and sometimes arise at opposing views, would add to our understanding of the current processes for early detection in breast cancer and assist those who seek to contribute to mammography screening policy, as well as those participating in consumer decisions about screening.

We conducted a detailed qualitative study of the views and opinions of Australian breast screening experts on a range of topics related to mammography screening. We used a framing approach to map and analyse experts' views on the issue of overdiagnosis. Framing describes the particular mind-set through which a topic is understood. The framing of an issue determines how the problem is conceived, what information is selected and the value judgements that are made. Different frames incorporate different, apparently self-evident, strategies to solve the perceived problem [17, 18]. Frames can be used in politics or by institutions to convey a particular message or point of view [19]. Frames are not only used as deliberate tools: they are also used by individuals, often unconsciously, as a way of thinking about and making sense of a complex topic. Framing theory is particularly well-suited to the study of overdiagnosis because it allows for a detailed examination of different viewpoints held, and used, by experts about this contentious topic. We present our analysis of how experts framed the topic of overdiagnosis in breast screening. Our research questions were:

- How do Australian breast screening experts frame overdiagnosis?
- How do those frames present the problems, causal elements, value judgements and solutions relevant to overdiagnosis?

Methods

This study is part of a larger Australian National Health and Medical Research Council (NHMRC) funded project examining ethical issues in cancer screening in Australia [20]. One component of the larger project was a qualitative study of contemporary issues in breast cancer

screening, using semi-structured interviews with influential breast screening experts. This paper is reporting on one aspect of this breast screening study. We defined “influential experts” as people working or researching in breast screening who influence the public, primary care practitioners and/or policy makers by engaging in one or more of: media commentary; academic or lay publications and presentations; senior service delivery management; membership of government advisory bodies, professional committees and/or non-government/consumer organisations related to breast screening. We sampled purposively from this population, seeking to obtain a wide diversity of views by inviting participants with a range of publicly aired positions [21]. We reasoned that perspectives on screening might be associated with professional backgrounds so we ensured that we included experts with a range of roles and responsibilities. See Table 1 for further participant details.

We identified potential participants by scanning academic and lay literature on breast screening, examining personnel lists on websites of government or non-

Table 1 Characteristics of experts

Participants 33 (Brackets contain number of experts who were invited but did not-participate; 13)	
Professional role*	Clinicians^ 15 (3) <ul style="list-style-type: none"> • Oncologists 3 (1) • Surgeons 4 (0) • Breast physicians 1 (2) • Radiologists 2 (0) • Radiation oncologists 2 (0) • Pathologists 3 (0) • Others [not otherwise specified; NOS] 0 (1) Non-clinical researchers 14 (3) <ul style="list-style-type: none"> • Epidemiologists/biostatisticians 9 (1) • Others [NOS] 5 (1) Administrators/managers 6 (2) Advocacy leaders 6 (7) <ul style="list-style-type: none"> • Consumers working in advocacy 3 (6) • Clinicians/researchers working in advocacy 3 (1)
Public stance on breast screening+	Supportive 16 (9) Mostly supportive# 3 (1) Critical 6 (0) Unknown to researchers 8 (3)

*note that some experts held more than one professional role
 ^Most clinicians engaged in research to a greater or lesser extent
 +We loosely categorised potential interviewees as being “supportive”, “mostly supportive” or “critical” about breast screening based on publicly available commentary
 #Broadly supportive of breast screening but with selected concerns about one or more elements of the program

government advisory and advocacy bodies involved in breast screening, and following up suggestions from colleagues and participants. We used information in the public domain to contact experts by email. Forty-six experts were contacted, and 33 (17 male, 16 female) participated in the study. Thirteen people either did not wish to participate (3), did not respond (9) or were unable to participate in the time available (1). We had a low response rate from senior community advocacy figures. Speculatively, this may have been due to a higher turnover of staff in these (largely volunteer) positions than in other professional roles. That is, the individuals may no longer have been contactable at the email addresses that we had access to. We continued sampling until we had good representation of a range of professional roles and until we reached thematic saturation in our analysis [22].

We used an interview format for in-depth exploration of the views and reasoning of experts. LP conducted semi-structured interviews from October 2012 to October 2013, meeting in the participant's or her own workplace, or talking over telephone if unable to meet in person. The interviews lasted between 39 and 105 min (average 66 min) and there was no observed difference between face to face and telephone interviews in terms of quality or length [23]. At the beginning of each interview, LP discussed her interest in the topic with the expert, explaining that she was a medical practitioner with clinical experience in breast screening, currently undertaking doctoral studies in cancer-screening ethics. She clarified that the purpose of the interviews was to glean the range of opinions amongst Australian experts about breast screening. The interviews drew loosely on a set of core questions designed to draw out the participant's views. We also sought to tailor each interview to the particular expertise and interests of the participants, and explored the leads and topics that arose throughout the discussion [22, 24]. We encouraged the participants to talk about overdiagnosis, asking generally for interviewees' views on this topic, without pre-empting ideas about what might be considered important. We only pursued particular lines of enquiry about controversial elements – as informed by the literature – if this flowed on from preceding comments of the participant. An additional file outlines sample interview questions (see Additional file 1).

The interviews were taped, transcribed and de-identified. We used an inductive analytic methodology, developing a set of categories that captured the most important views and values in the experts' comments. Each interview was read repeatedly and coded in detail to capture views and values relevant to overdiagnosis. The analysis was conducted as an iterative process comprising detailed coding of individual transcripts (LP) and discussion and revision of the findings in group analysis

meetings (all authors). We used framing theory to organise and understand different ways that experts thought about overdiagnosis, identifying the dominant frames in use and categorising important elements of each frame in terms of problems, causes, solutions and moral evaluation [18].

Ethics approval was granted from the Cancer Institute NSW Population & Health Services Research Ethics Committee [HREC/12/CIPHS/46] and the University of Sydney Human Research Ethics Committee [#15245]. All participants gave individual consent to be interviewed, and were free to withdraw from the study at any stage.

Results

We identified six frames that Australian breast screening experts used with regard to overdiagnosis (Table 2).

Frame 1: overdiagnosis is harming women

"I would like to see breast cancer eradicated too but not at the expense of ... potentially treating them with serious treatments for a condition that maybe didn't need to be found in the first place... To me, it's all about how do we run this program in a way that minimises the harm ... without losing the benefit."
(Expert #33, clinician)

Experts who used this frame were passionate about the topic of overdiagnosis in breast screening and saw it as a major threat to the wellbeing of women. The frame emphasised both quantity and quality of harm. Harm quantity was described in terms of the high number of overdiagnosed cases compared to the number of lives saved by screening. Harm quality was discussed by highlighting the serious negative impact from each case of overdiagnosis, including both the psychological impact of a breast cancer diagnosis on a woman and her female relatives (for whom it has perceived risk implications), and the short and long term impact of unnecessary treatment on lifestyle and physical health. This framing of overdiagnosis as a serious problem was grounded in a strong commitment to avoiding harm in any public health program.

This frame encompassed two categories of solution. Experts who were enthusiastic about the potential benefits of screening suggested reducing overdiagnosis through a targeted, personalised screening program, matching recommended screening frequency to breast cancer risk as determined by factors such as breast density. This would enable the population to simultaneously retain benefits of screening and reduce harms. Experts who were more sceptical about the benefits accruing from breast screening preferred a more extreme solution: reducing overdiagnosis by decreasing overall breast screening participation. However, they assumed that cessation of public funding for the program was politically unlikely, and promoted more

Table 2 Overdiagnosis frames adopted by Australian breast screening experts

Frame	Defining the problem	The reasons for the problem	Value judgement	Proposed or implied solution
1. Overdiagnosis is harming women	Breast screening is resulting in significant harm to women because of overdiagnosis	The harms associated with overdiagnosis are significant in both quantity and quality	Breast screening programs should pay more attention to avoiding the serious harms of overdiagnosis	Reduce overdiagnosis either by performing targeted screening or by reducing screening overall
2. Stop squabbling in public about overdiagnosis	The public discussion of overdiagnosis is generating negative publicity which may reduce breast screening participation & is therefore a disservice to women	Exaggeration of harms in public debates is causing confusion amongst women and threatening participation rates.	Breast screening commentators should give priority to delivering health benefits (saving lives)	Confine discussion about overdiagnosis to academic circles only, avoiding public confusion
3. Don't hide the overdiagnosis problem from women	The breast screening program is not facilitating informed choice amongst women	There is a deliberate lack of communication about overdiagnosis from breast screening providers because of a desire to maximise breast screening participation	Breast screening should give absolute priority to promoting autonomy via informed choice	Fully inform women about overdiagnosis
4. We need to know the overdiagnosis rate	It is not clear how much overdiagnosis is present in breast screening	There is huge variation in overdiagnosis rates due to different methodologies and/or data sets; differences in the way overdiagnosis figures are presented hampers interpretation by non-epidemiologists	Overdiagnosis research should be more rigorous, robust and consistent	Commit to reaching a consensus on appropriate methodology & the way we report the figures
5. Balancing harms and benefits is a personal matter	It is not clear how to compare the harms & benefits of breast screening	It is impossible for experts to definitively compare harms & benefits because they are qualitatively different	Breast screening decision making should be guided by a consumer-orientated process, which takes into account public attitudes to harms and benefits	Use deliberative methods to inform policy decisions; support individual consumers to make personal decisions about participation
6. The problem is overtreatment	Breast screening is resulting in overdiagnosis which leads to overtreatment of some women	Management of some women with cancer is sometimes unnecessarily aggressive because we don't know enough about the natural history of screen detected lesions	While it is important that screening continues to save lives, we should seek ways to reduce harms from unnecessary (over) treatment	Ongoing education for pathologists; renaming non-invasive lesions; research into prognostic biomarkers, targeted treatments & less aggressive management regimes; patient centred care

realistic solutions such the removal of governmental promotions and personalised screening invitations.

Frame 2: stop squabbling in public about overdiagnosis

"I feel that it's unwarranted ... when ... the [overdiagnosis] debate is mentioned in a way that it might deter people from actually participating in screening. I think that's really counterproductive... The debate should be managed in a way that it's not inadvertently discouraging screening." (Expert #10, consumer advocate)

This frame centres on the negative publicity generated by overdiagnosis discussions and the decrease in breast screening participation that might ensue. Underlying this concern is a firm belief in the net benefit of breast screening and a strong desire to have women avail themselves of life-saving opportunities. The frame delivers a choice between life and overdiagnosis: *"saving a life is*

more important than the harm that's caused in damaging normal breasts." (Expert #3, clinician). Experts using this frame regarded overdiagnosis as a minor problem, for several reasons. Firstly, and most commonly, it was seen as an inevitable part of screening, particularly breast screening where cancer growth is variable and unpredictable. Secondly, the number of overdiagnosed cases was considered low relative to the total number of breast cancers picked up through the program. Finally, the harm associated with each overdiagnosed case was seen as low. This was justified in several ways: 1) individual women could not know whether or not their cancer was a case of overdiagnosis; 2) women (allegedly) disregarded the concept of overdiagnosis when considering treatment options; and 3) treatment for small, low-grade cancers (ie those most likely to be cases of overdiagnosis) was viewed as relatively benign. In addition to the lack of harm, the frame highlighted possible benefits from overdiagnosis. Although, by definition, an overdiagnosed cancer will not itself threaten a woman's life, experts suggested that as the

woman would be at increased risk of a second breast cancer she would benefit from being identified and treated with tamoxifen.

In this frame, personal autonomy and informed choice were important values in healthcare. However experts rejected the idea that stopping 'squabbling in public' might conflict with respecting women's autonomy. Their central concern was not so much that overdiagnosis was mentioned, but that overdiagnosis was invariably (mis) represented as an important harm:

"Harm is a term that's been developed by academics, along academic lines... There's a possibility of over diagnosis ... it's not very much ... you shouldn't call that harmful." (Expert #17, consumer advocate)

Some experts used this frame with the view that informed choice was an unattainable goal, because overdiagnosis in breast screening is just so complex:

"There's all this business of informed consent. Well, frankly, I think it's for the birds. I think it's a very difficult thing for people to have informed consent. When people argue a lot, you know, people that are informed, supposedly, argue, I don't know how you give informed consent. It's very difficult for the average layperson to understand." (Expert #9, clinician)

There was also moral condemnation of the particular impact that negative publicity has upon disadvantaged women. This group was presented as being particularly likely to be confused by public debates, and vulnerable to screening disengagement:

"There's probably people in the [suburbs of lower socioeconomic status] who stop going to screening. Because they're not as sophisticated ... and they come from non-English speaking backgrounds. The message they get is that screening is not needed... It's okay if you're in the [suburbs of higher socioeconomic status] because you'll keep coming anyway." (Expert #29, clinician)

In this frame, appropriate solutions focussed on preventing a fall in participation rates. They included: avoiding any implication that overdiagnosis is a harm; keeping discussions confined to academic circles; and informing women about overdiagnosis only when attendance is secured (such as at the point of mammogram or after diagnosis).

Frame 3: don't hide the overdiagnosis problem from women

"We should absolutely tell people, 'These are the benefits, these are the harms'; and some people say that public health benefits should be what we are aiming for, but for me I think you absolutely cannot compromise on telling people. It's just not something I'm prepared to do." (Expert #23, researcher NOS)

This frame centres on the lack of communication about overdiagnosis from screening providers to women. Experts acknowledged that while some women prefer a simple advisory message about breast screening, others want an informed decision making process, with the readily available and easily-understood information. The current lack of communication about overdiagnosis was presented as a deliberate strategy by screening providers to avoid risking a decline in participation. In this frame, informed choice was an absolute right for individual women, taking priority over the delivery of population health benefits.

The solution was to make information about overdiagnosis available to women, despite the inherent complexities in the topic and the tension with trying to encourage participation:

"I agree with you that the experts can't agree and how do you talk to women about it, and it is a very complex area and hard to talk about, but clearly an important issue in the context of screening... I think you have to share with women your uncertainty." (Expert #25, epidemiologist)

This frame accommodated a variety of solutions ranging from detailed publicising of overdiagnosis information in every screening pamphlet and advertisement, to making detail of possible harms from screening available upon request. In this frame provision of information could co-exist alongside government promotion of screening.

Frame 4: we need to know the overdiagnosis rate

"There is a recognition that there are tumours found that are either frankly non-progressive or are likely to progress so slowly they don't matter. I don't think too many people would say, 'Well that wouldn't exist at all'. The argument is over how much and the scale of that." (Expert #22, epidemiologist)

In this frame, the main problem was overdiagnosis measurement and quantification. Experts spoke of overdiagnosis as being of indeterminate significance because of uncertainty about the overdiagnosis rate. They saw the

wide range of estimates as a central conundrum, possibly explainable by different methodologies and variable data sets. A subsidiary problem was the inconsistent presentation of overdiagnosis figures, variably portrayed as acceptably low by comparing with the (large) number of cancers diagnosed, or as unacceptably high by comparing with the (smaller) number of lives saved by screening. This made it difficult to compare studies and understand the implications of overdiagnosis. In this frame sloppy research methods aimed at generating quick or provocative publications were a particular problem, eliciting strong disapproval. The first step to solving this quantitative problem would be to reach consensus on the most reliable and robust ways to calculate and present overdiagnosis.

Frame 5: balancing harms and benefits is a personal matter

"Descriptively they're quite different ... I don't think there is any formula for the balance... It's very subjective of the balance of disparate outcomes." (Expert #20, clinician)

Through this frame, the problem was comparing harms and benefits of breast screening. Experts discussed both overdiagnosis harms and mortality benefits accruing from breast screening. They suggested that while each are likely to be important to women, current estimates about their rates meant that harms and benefits were closely balanced; in this situation, qualitative differences between the two made it impossible for experts to draw exact conclusions about where and when equipoise arose. In this frame, such uncertainty required that the public should assist with decision making. Experts explained that since individual attitudes to harms and benefits would determine what was perceived as the net outcome of screening, the process of decision making needed consumer input: it was insufficient to rely on pre-determined program values or system priorities. The frame encompassed two possible solutions. Some experts discussed seeking public assistance with decision making at the policy level, using a deliberative process such as a citizens' jury to make a ruling about the balance between benefits and harms:

"I believe that for a lot of screening things there should be a community jury. There are some things that are obvious, that we can just proceed with them, but other things where there's a balance between the benefits and harms, I think we need some sort of deliberative democracy process." (Expert #21, researcher NOS)

Others spoke of more explicit attempts to achieve informed consumer decision making, encouraging women to consider the net value of screening for themselves as

individuals. They suggested screening participation decisions should be based on women's personal priorities rather than potentially coercive input from screening providers.

Frame 6: the problem is overtreatment

"I don't really believe in overdiagnosis as such. I mean, I think there's over treatment ... Finding it is not the issue. Treating – how it's treated is the issue, as I see it." (Expert #9, clinician and provider)

The final frame through which overdiagnosis was understood purposefully separated the treatment process from the screening process, and presented the problem as arising from treatment decisions. Several causal elements for the growing problem of overtreatment were presented: some experts spoke of the increasing sensitivity of radiological equipment, meaning that more and more lesions were identified. Others noted that diagnostic criteria for certain pathological entities were vague, and *"not ... easy to get inter-observer agreement on."* (Expert #28, clinician) They discussed resulting disagreements about the threshold for atypia, with tendencies amongst some pathologists for 'overcalling' cancer so that benign changes were more likely to be named and treated as borderline lesions. Finally, experts commented on the limited research around natural history and management guidelines for low-risk lesions. Expert #28, (clinician) noted that, *"a lot of those guidelines are based on reviews of data which are not robust"* and suggested that they were instead driven by clinicians' observer bias and accepted by women with high levels of anxiety and fear. Women with low-risk lesions were perceived as undergoing aggressive treatments while, *"you really wonder whether any of it was actually necessary."* (Expert #13, clinician)

In this frame, both mortality benefit and harm avoidance were valued. Thus appropriate solutions in this frame maintained current screening parameters, and only altered downstream elements. Experts presented a range of solutions including: regular pathology updates on diagnostic criteria and thresholds; research into better prognostic tools (such as biological markers of aggression); development of more targeted / less harmful therapies, research into less aggressive treatment regimes for low-risk lesions; and patient-centred care for women with borderline lesions, relying on correlation between clinical, radiological and pathological findings to make a diagnosis and plan the management, rather than following set guidelines.

How experts used frames

Each expert used between one and four frames. Some experts employed two or more moderately incommensurable frames, and were often conscious of inherent contradictions. For example Expert #7 (clinician) used

both the “stop squabbling in public” and “stop hiding the problem” frames, acknowledging the possible inconsistency of this position. However, none of the experts’ discussions combined frames that were strongly incommensurable, for example, no experts used both the “overdiagnosis is harming women” and the “stop squabbling in public” frames. The “stop hiding the problem” frame was the most commonly used, and was adopted by experts working across all roles except consumer representation/advocacy. All (three) consumers working in advocacy roles used the “stop squabbling in public” frame.

There were observable patterns between experts’ overall views on breast screening and their use of overdiagnosis frames. All experts who were critical of breast screening used the “don’t hide the problem” frame, and none of them used the “stop squabbling in public” frame. Experts who were supportive of breast screening used one or other, but not both, of these frames (in approximately equal numbers), and were the only group to use the “stop squabbling in public” frame. Further detail on this is available in Additional file 2: Table S1-S2).

Discussion

It is recognised in the breast screening literature that experts hold differing opinions about overdiagnosis, but the basis for those differences has not been explored. We identified six overdiagnosis frames in use by Australian breast screening experts and analysed the elements of each frame. There was considerable variation between frames, in terms of: how overdiagnosis was problematised, what information was highlighted as being relevant, what values were prioritised as being important, and what solutions were suggested. These multiple points of difference explain much of the controversy and disagreement that surrounds this important topic.

To our knowledge, there has been no detailed empirical study on what and how breast screening experts think about overdiagnosis. Some journals have presented debates containing opposing arguments as a way of exploring some of the diversity within this topic [25, 26]. Others have published letters to the editor in response to controversial elements within breast screening articles [27]. Our work builds upon and extends the existing literature, providing a comprehensive analysis of the frames used to talk about and understand overdiagnosis in breast screening. Previous research has suggested that consumers are largely unaware about overdiagnosis [12], but nevertheless an important avenue for future research would be to investigate whether women have pre-existing ideas and concerns about aspects of overdiagnosis that have not been captured within the frames presented here.

An understanding of the elements within different overdiagnosis frames will help those who work in, or consider participating in breast screening [28, 29]. The

different frames may be a useful scaffold upon which to generate thoughtful discussion amongst practitioners. These frames also offer new tools for experts to clarify their own positions and to understand the opinions of others on overdiagnosis including views on whether and how it is a problem, and what solutions might be appropriate. This may facilitate recognition of points of agreement and form a basis for co-operative dialogue in the best interests of consumers [19]. Policy makers are faced with a baffling array of suggestions about what, if anything, should be done with regard to breast screening overdiagnosis. The experts who participated in this study offered a range of solutions, focusing on different points along the screening journey, including primary research, evidence translation and presentation, communication with consumers, screening practices, diagnostic practices, and treatment. By viewing these solutions in connection with the frame to which they belong, it becomes easier to see why one solution might be preferred over another, and by whom. Any management plan or policy is likely to need multiple solutions, and incommensurability between some frames will necessitate compromises and negotiations.

This study benefits from the open qualitative methodology, which allowed us to explore a topic about which there was little pre-existing knowledge. We were able to access the views and opinions from a range of influential individuals and expert stakeholders from different parts of Australia. Its strength lies in the depth of its enquiry and its ability to capture the complexity of the evidence base and value judgements underlying the range of different views. As with much qualitative work, we cannot make any predictions about the prevalence or pattern of our results within the wider population, and this may be a useful avenue for future survey research. While this study was limited to the Australian setting, much of the developed world has organised breast screening programs, comparable values, and access to the same body of scientific evidence, and thus the findings are likely to be broadly applicable across these countries. It is possible that experts who participated in our study were somehow different from those who were invited but did not participate. We sought to minimise any bias of this sort by ensuring that we interviewed experts with a range of attitudes to screening, and a wide variety of professional roles and experience.

Conclusions

Our results demonstrate that experts approach overdiagnosis in various ways, see a range of issues and values at stake, and are inclined to promote different solutions. This may be an important contributor to the ongoing controversy in this topic, and offers a new explanation for why some debates about overdiagnosis are so heated. The concept of experts using different frames when

thinking and talking about overdiagnosis might be a useful tool for those who are engaged in the topic, assisting with communication and facilitating better understanding of others' viewpoints.

Additional files

Additional file 1: Sample interview introduction and questions (note: this list is provided as a guide only; the questions were modified to suit the experience and perspective of the interviewee). (DOC 30 kb)

Additional file 2: Table S1. Overdiagnosis frames used by experts (organised according to main professional role). **Table S2.** Overdiagnosis frames used by experts (organised according to attitude to breast screening). (DOCX 35 kb)

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

LP initiated and performed the study, and prepared the first and subsequent drafts of the paper. LR and SC assisted with study planning and data analysis and made substantial contributions to draft revisions. All authors read and approved the final manuscript.

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Additional file 1: Sample interview introduction and questions

Note: this list is provided as a guide only; the questions were modified to suit the experience and perspective of the interviewee.

Thank you for agreeing to participate in this study. As you know, there has been quite a lot written in the literature and in the media about breast screening and what the program should look like. Plenty of people are happy with things the way they are, but others are not. So I'm interested in exploring that range of opinion, particularly amongst people who work in the field, including those who work in clinical practice, research, administration, or in breast cancer advocacy.

- Can you describe the scope of your professional activities that involve breast screening, to give me an idea about your involvement in the program?

- Would you like to see any changes to the current program?
 - *Prompt:* What would your ideal program be?

- There are many different ideas about breast cancer screening. Can you comment on these?
 - *Prompt:* There are some who hold very extreme views about breast cancer screening. How do you respond to these ideas? What do you think drives those views?

- *(If the topic hasn't yet surfaced)* Recent studies suggest that some cancers found at screening would never have come to clinical attention in that person's lifetime; for example, Marmot and colleagues suggest that for every 1 life saved by breast screening there are 3 cancers overdiagnosed. What are your thoughts on this issue?
 - *Prompt:* e.g. is it – non-existent; existing but not a problem; a problem
- *(if appropriate to expert's views)* What level of overdiagnosis do you work with?
- *(if considered a problem)* Should screening programs take any responsibility for reducing overdiagnosis? e.g. should we tailor the program to minimize overdiagnosis?
- *(if expert talks about the development of biomarkers or other prognostic tools as a way of addressing concerns about overdiagnosis)* What should we do in the meantime?

Additional file 2: Tables 3 & 4

Table 6.3 Overdiagnosis frames used by experts (organised by main professional role)

Expert profession [#]	Frame 1: Overdiagnosis is harming women	Frame 2: Stop squabbling in public about overdiagnosis	Frame 3: Don't hide the overdiagnosis problem from women	Frame 4: We need to know the overdiagnosis rate	Frame 5: Balancing harms & benefits is personal	Frame 6: The problem is overtreatment
clinician			x			
clinician			x			
clinician			x	x		x
clinician			x			
clinician			x			
clinician			x			x
clinician	x		x			
clinician						x
clinician				x	x	
clinician			x			
clinician			x			
clinician			x			
clinician		x				
clinician		x				x
epidemiologist*	x		x	x		x
epidemiologist			x		x	
epidemiologist			x	x		
epidemiologist	x		x			
epidemiologist			x	x		
epidemiologist			x			
epidemiologist				x		
epidemiologist		x				
researcher [^]	x		x		x	
researcher						
researcher			x			
researcher		x				
advocate [#]		x				
advocate		x				
advocate		x				x
administrator		x				
administrator			x			

NOTE: [#]Experts who held more than one professional role are classified under their main role. *This category includes epidemiologists and biostatisticians. [^]This category includes all non-clinical researchers who are neither epidemiologists nor biostatisticians. [#]Clinicians and researchers who worked in advocacy are categorised under their main role.

Table 6.4 Overdiagnosis frames used by experts (organised according to attitude to breast screening)

Expert's public position on breast screening	Frame 1: Overdiagnosis is harming women	Frame 2: Stop squabbling in public about overdiagnosis	Frame 3: Don't hide the overdiagnosis problem from women	Frame 4: We need to know the overdiagnosis rate	Frame 5: Balancing harms and benefits is personal	Frame 6: The problem is overtreatment
supportive			x			
supportive		x				
supportive		x				
supportive		x				x
supportive		x				
supportive			x	x		
supportive			x			
supportive			x			
supportive				x	x	
supportive			x		x	
supportive			x			
supportive			x			
supportive			x			
supportive		x				
supportive		x				x
mostly supportive			x			
mostly supportive			x	x		x
mostly supportive			x			
critical	x		x			
critical	x		x		x	
critical			x	x		
critical	x		x			
critical	x		x	x		x
unknown			x			
unknown			x			x
unknown						x
unknown				x		
unknown			x			
unknown						
unknown		x				
unknown			x			

NOTE: mostly supportive = broadly supportive of breast screening but with selected concerns about one or more elements of the program.

Chapter 7: The role of communication in breast cancer screening

7.1 Chapter introduction

This chapter contains the following publication and additional online files:

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RESEARCH ARTICLE

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The role of communication in breast cancer screening: a qualitative study with Australian experts



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Abstract

Background: One well-accepted strategy for optimising outcomes in mammographic breast cancer screening is to improve communication with women about screening. It is not always clear, however, what it is that communication should be expected to achieve, and why or how this is so. We investigated Australian experts' opinions on breast screening communication. Our research questions were: 1 What are the views of Australian experts about communicating with consumers on breast screening? 2 How do experts reason about this topic?

Methods: We used a qualitative methodology, interviewing 33 breast screening experts across Australia with recognisable influence in the Australian mammographic breast cancer screening setting. We used purposive and theoretical sampling to identify experts from different professional roles (including clinicians, program managers, policy makers, advocates and researchers) with a range of opinions about communication in breast screening.

Results: Experts discussed the topic of communication with consumers by focusing on two main questions: how strongly to guide consumers' breast cancer screening choices, and what to communicate about overdiagnosis. Each expert adopted one of three approaches to consumer communication depending on their views about these topics. We labelled these approaches: Be screened; Be screened and here's why; Screening is available please consider whether it's right for you. There was a similar level of support for all three approaches. Experts' reasoning was grounded in how they conceived of and prioritised their underlying values including: delivering benefits, avoiding harms, delivering more benefits than harms, respecting autonomy and transparency.

Conclusions: There is disagreement between experts regarding communication with breast screening consumers. Our study provides some insights into this persisting lack of consensus, highlighting the different meanings that experts give to values, and different ways that values are prioritised. We suggest that explicit discussion about ethical values might help to focus thinking, clarify concepts and promote consensus in policy around communication with consumers. More specifically, we suggest that decision-makers who are considering policy on screening communication should begin with identifying and agreeing on the specific values to be prioritised and use this to guide them in establishing what the communication aims will be and which communication strategy will achieve those aims.

Keywords: Breast cancer, Mass screening, Communication, Decision making, Ethics, Qualitative research, Mammography

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Background

Mammographic breast screening opportunities and programs have been introduced in many high-income countries over the past three decades [1–3], with the expectation of achieving significant population breast cancer mortality reduction. This outcome was suggested by evidence from early randomised control trials (RCTs) and cohort studies [1, 2] and later backed up by further studies and multi-study reviews [4, 5]. In Australia the government provides free biennial screening mammography for all women over 40 years of age through its national program *BreastScreen Australia* [6]. The government actively encourages the regular participation of women aged 50–74 years, with promotional communications focusing on this target age range [7]. An important focus of breast screening research has been how to communicate effectively with women in order to achieve high screening participation rates and realise the mortality benefits described in the literature [8].

At the same time there has been growing interest in encouraging and supporting members of the public to be more informed about health matters, including screening, and more engaged in decisions about their own healthcare [9–13]. This is partly underpinned by a desire to respect the autonomy of patients and healthcare consumers [14–16] and partly for reasons such as engendering greater public satisfaction, more efficient use of healthcare services and possibly even better health outcomes for individuals and communities [17–19].

More recently, uncertainties about both benefits and harms of breast screening have emerged. The benefits may be less than first anticipated from the early studies. Meta-analyses of what is by now a substantial body of RCT evidence on mammographic breast screening provide different estimates of benefit, depending on which of the RCTs are considered to be of sufficiently high quality to include in the review [20, 21]. There are also suggestions that the RCT evidence may be out of date, with recent improvements in breast cancer treatment together with increased awareness about prompt symptomatic presentation leaving less room for screening to have a beneficial effect [22, 23]. At the same time, a growing body of research is contributing to concern about harms associated with breast screening, including cumulative false positive tests [22] and overdiagnosis (the diagnosis of non-progressive or slowly progressive breast cancer through screening, a diagnosis that does not produce a net benefit for the woman diagnosed) [24–27]. The amount and significance of overdiagnosis harm is particularly contentious [23]. There is concern about whether or not hearing about these uncertainties and harms will deter women from screening, and indeed recent RCT evidence does suggest that women who are more informed about overdiagnosis express a

lower intention to screen [28]. A perceived tension has thus arisen between the aim of achieving high breast screening participation rates and the aim of enabling women to make informed choices about screening, with debate about whether communication with consumers should focus on maximising participation or on communicating to support citizen's knowledge and autonomy [29].

Official government policy endorses shared decision making to achieve informed choice in healthcare generally and in screening more specifically [30, 31]. Many claim that informed choice is particularly pertinent to screening because it actively targets healthy people rather than sick people who are seeking help for symptoms. Others highlight the importance of informed choice in those screening programs for which evidence about outcomes is insufficient or controversial, or where benefits and harms are finely balanced such that individual values become relatively more important in guiding decisions about being screened [32, 33]. There have been concerns that government directives to facilitate informed choice are not being adequately followed within breast screening [29, 34–36], with international criticism of breast screening information pamphlets on the grounds that they withhold important information about possible harms of breast screening [37–40], and suggestions that consumers should be explicitly encouraged to make their own choice whether or not to attend screening [36, 41, 42]. Not all authors prioritise the target of achieving informed consumer choice in cancer screening. Some prefer to focus on achieving adequate uptake in order to realise screening benefits [43]. Others have concerns about the process or reasoning behind such a target. For example, some writers suggest that it may be unreasonable to expect even fully informed citizens to take on what they depict as the burdensome task of decision making for cancer screening: weighing up uncertain benefits and harms, about which experts disagree [44]. Others contend that requiring or encouraging informed citizen decision making about cancer screening may be unnecessary since, arguably, justification for it may rely on an inappropriately narrow version of autonomy [45]. According to this view, a respectful approach should accommodate citizens who wish to rely on others to guide or choose for them. Finally, some argue that providing citizens with enough information to make fully informed screening choices may be prohibitively time consuming [46].

It is well-recognised that there are differences of opinion amongst clinicians regarding the involvement of patients in decision making for clinical care [47] and it is known that there are differences in how frequently or enthusiastically primary care practitioners discuss mammographic breast screening with their patients [48–50].

The ongoing discussions in the academic literature about the aims and content of breast screening communication suggests there is also likely to be diversity of expert opinion about policies for consumer decision making in relation to breast screening [29]. We could find no empirical work that examined this topic and to fill this gap we investigated the opinions and priorities of influential Australian experts with respect to breast screening communication with consumers. Our research questions were:

- What are the views of Australian experts about what and how we should communicate with consumers about breast screening?
- How do experts reason about this topic and how does this explain the positions they take?

Methods

Methodology

Our study was part of a larger project exploring the social and ethical issues around cancer screening in Australia [51]. Data collection from experts in breast screening was undertaken as a sub-study in the project, and this paper reports on one component of the sub-study. Other components of the sub-study involving analysis of different aspects of the data set have been written up separately [52]. We used an empirical, qualitative methodology. The emerging research field of “empirical bioethics” uses empirical research methods alongside traditional theoretical ethics in the context of healthcare and other biological sciences. Empirical methods are used to study and describe an ethical issue; theory is used to varying degrees by different researchers to shape the empirical study and inform interpretation and discussion of findings. We situate ourselves close to the style of Frith [53], who combines empirical and theoretical ethics in a symbiotic relationship, arguing that each can and should, inform each other [54]. We used sampling, data collection and analysis strategies that were best suited to the particular circumstances and aims of our project, and enabled us to conduct our study with internal coherence [55–58].

Participants and sampling

We sought to include influential breast screening experts from within Australia as participants. We defined influential experts as people with experience of working in a field directly related to breast screening in Australia and who had influence through one or more of: senior service delivery; academic or lay publication; membership of government or professional advisory committee; senior position in non-government breast screening organisation or consumer group. We sought to maximise the diversity of perspectives amongst our participants by deliberately seeking experts known to have publically expressed divergent opinions about breast screening

(loosely categorised by us as being “supportive”, “mostly supportive” or “critical”) and experts from a range of professional roles across Australia including clinical practice, research, program administration, advisory staff and consumer advocacy.

We identified potential participants by reading local academic and lay literature; scanning personnel lists on websites of government and non-government organisations; and following up on suggestions from previously interviewed experts and from colleagues involved in cancer screening research. We approached 46 experts via email and interviewed 33 (17 males, 16 females). The remainder were unavailable (1), unwilling (3) or did not respond (9). We had a particularly low response rate from volunteers in consumer advocacy roles, which may have been at least partly due to a higher turnover of people in these positions than in other professional roles – that is, they may no longer have been acting in a senior advocacy capacity when our email was sent.

We performed our analysis in parallel with data collection, and used the information in the early interviews to direct further sampling, aiming to capture and explore the range of different ideas about this topic. We continued sampling until we were satisfied that we had sufficient diversity of opinions and roles [58] (Table 1) and until we were no longer hearing any new information. (thematic saturation) [54, 57].

Data collection

LP conducted semi structured interviews between October 2012 and October 2013. The interviews lasted an average of 66 min (range 39–105 min) and were conducted in the expert’s or in LP’s workplace, or by telephone if unavailable to meet in person. Making use of telephone interviews enabled us to speak with experts from disparate locations around the country and we found that telephone interviews were similar in quality and length to face-to-face interviews [59].

LP discussed her interest in the topic with experts, explaining that she was a medical practitioner with clinical experience in breast screening, currently undertaking doctoral studies in cancer-screening ethics. She informed participants that the purpose of the interviews was to glean the range of opinions amongst Australian experts about breast screening. They were asked about their general attitudes to the current program, their suggestions and hopes for the future of the program, and their opinions on communicating with consumers (Additional file 1). The interviews were digitally recorded, professionally transcribed and any identifying information (such as person or place names) that was articulated during the discussion was removed from the transcripts before analysis began.

Table 1 Characteristics of experts

Participants 33 (Experts who were invited but did not-participate 13)	
Professional role ^a	Clinicians ^b 15 (3)
	Oncologists 3 (1)
	Surgeons 4 (0)
	Breast physicians 1 (2)
	Radiologists 2 (0)
	Radiation oncologists 2 (0)
	Pathologists 3 (0)
	Other 0 (1)
	Non-clinical researchers 14 (3)
	Epidemiologists/ biostatisticians 9 (1)
Other 5 (1)	
Administrators/ managers 6 (2)	6 (2)
Advocacy leaders 6 (7)	Consumers working in advocacy 3 (6)
	Clinicians/researchers working in advocacy 3 (1)
Public stance on breast screening ^c	Supportive 16 (9)
	Mostly supportive ^d 3 (1)
	Critical 6 (0)
	Unknown to researchers 8 (3)

^anote that some experts held more than one professional role, for this reason the numbers attached to specific professional roles do not neatly add up to $n = 33$ (participants) or $n = 13$ (experts invited but not participating)

^bmost clinicians engaged in research to a greater or lesser extent

^cWe loosely categorised potential interviewees as being "supportive", "mostly supportive" or "critical" about breast screening based on publicly available commentary

^dbroadly supportive of breast screening but with selected concerns about one or more elements of the program

Analysis

Analysis involved iterative reading, coding and categorisation of interview data. We sought to identify and understand the range of attitudes and underlying values that experts expressed around the topic of consumer communication. Repeated reading was undertaken in conjunction with the generation of a set of codes that captured attitudes and values, and the development of more abstract categories, that evolved as data collection and analysis progressed. LP wrote case-based memos throughout the project and shared these and provisional analysis with the other authors [58]. All authors contributed to ongoing analysis, involving comparison between codes and data, revision of findings and development of concepts presented in this paper.

Ethics approval

Ethics approval was granted from the Cancer Institute NSW Population & Health Services Research Ethics Committee [HREC/12/CIPHS/46] and the University of Sydney Human Research Ethics Committee [#15245]. All participants gave written or verbal informed consent

to their involvement in the study (those who were interviewed face to face gave verbal consent; those who were interviewed via telephone gave verbal consent). This research complies with current Australian laws and guidelines.

Results

Expert opinions on communicating with consumers

Experts spoke in detail about communicating with consumers regarding breast screening. Their comments focused on two issues: 1) the degree of guidance for consumers, and 2) the extent of information provided to consumers about overdiagnosis. Table 2 shows how experts' views on communication could be divided into three approaches according to the interaction between these two issues (guidance and overdiagnosis information). The first approach, which we have named "Be screened", combined guiding consumers towards screening with limited information on overdiagnosis. The second approach, "Be screened and here's why", combined guiding consumers towards screening with full consumer information. The third approach, "Screening is available, please consider whether it's right for you" combined no guidance about screening with full consumer information. We found a similar level of expert support for each of the three approaches. Logically there could potentially have been a fourth approach (no guidance and limited information – see Table 2) but there were no experts who advocated for this position. All experts were in favour of either guidance or full information or both; there were no experts who would recommend no guidance and no means for consumers to make an informed choice of their own.

Overall more experts preferred guiding women to be screened, and overall more experts preferred that full information be provided. Examining Table 2, and recalling that there were approximately the same number of experts in each cell, reveals why. Two out of three approaches ("Be screened" and "Be screened and here's why") supported guidance to screen. Two out of three approaches ("Be screened and here's why" and "Screening is available") supported the provision of full information on overdiagnosis. Thus providing guidance, and providing full information, were preferred to the alternatives.

Expert descriptions of what it means to guide consumers to be screened, or not

The detail in Table 2 describes experts' ideas of what it means to guide consumers to be screened, or not. The majority argued that consumer communication should include guidance towards screening. They endorsed the existing strategy whereby the screening provider is the main source of guidance. They also approved of current participation targets for screening units, suggesting they

Table 2 Experts' preferences regarding guidance and information when communicating with women about breast cancer screening

	Guidance ^a	No guidance ^b
Limited information ^c	"BE SCREENED" ^e	N/A
Full information ^d	"BE SCREENED AND HERE'S WHY" ^e	"SCREENING IS AVAILABLE, PLEASE CONSIDER WHETHER IT IS RIGHT FOR YOU" ^e

^aGuidance: Experts who preferred guiding women to screen advocated for the following:

- Provider-to-consumer guidance to screen via public promotional advertising & personalised letters of invitation to women from the screening program
- Marketing support & participation targets for local breast screening units to ensure guidance is effective at maintaining high participation
- Educational support & electronic reminders to enhance GP-to-consumer guidance to screen

^bNo guidance: Experts who preferred not to guide women's screening choices advocated for the following:

- An independent body to provide information to women about screening options & encourage them to make a thoughtful choice about participation
- Online decision aid tools available to consumers
- No personalised invitations

- Targets for consumer understanding rather than participation
- Educational support to enhance GP assistance for women to make an informed screening choice
- Directed advice available from GP upon request

^cLimited information: Experts who preferred limiting the overdiagnosis information presented to women advocated for the following content in consumer communications:

- Information that breast screening saves lives
- Information that a recall does not necessarily mean you have cancer
- Brief mention that overdiagnosis is a possibility and that it is unlikely
- Advising that further information is available to women upon request

^dFull information: Experts who preferred providing full information to women advocated for the following content in consumer communications:

- Detailed information about mortality benefit, false positives & overdiagnosis associated with breast screening
- Numerical / pictorial comparison of chances of deriving benefit & being overdiagnosed

^eThere were roughly equal numbers of experts supporting each of the three named approaches

were a useful tool for developing and maintaining a successful guidance strategy. Several experts advocated extending and enhancing consumer guidance by providing greater marketing support to local screening units, along with education and reminders for primary care practitioners to take a more active role in promoting breast screening.

A smaller number of experts recommended against guiding women to participate in screening (Table 2). These experts suggested that consumers be educated about the availability of screening, encouraged to understand benefits and harms, then asked to carefully consider whether or not the program was right for them. They recommended that communications with consumers be written by an independent body, suggesting that providers were likely to view and/or present screening in a favourable light. These experts were in favour of replacing participation targets with targets around information provision or public understanding of screening. They opposed personalised letters of invitation, suggesting that these carried the weight of government support and would therefore be seen by women as persuasive, even coercive. A couple of experts explicitly suggested that women should be given assistance with decision making, discussing strategies such as online decision making tools and primary care practitioner support in understanding the evidence and making choices in accordance with consumers' personal values. They suggested that guidance about screening could be made available for those who wanted it.

Expert descriptions of what it means to inform consumers about overdiagnosis, or not

Experts described two approaches to information about overdiagnosis (Table 2). The majority of experts thought

that information about overdiagnosis should be limited. These experts thought consumer communications should impart simple, uncomplicated information about screening benefit, with limited detail on possible downsides. They suggested overdiagnosis information should be presented briefly along the lines of, "some of the things that we are going to be treating you for may not progress." (Expert #33, clinician and provider) These experts proposed that further information could be made available for those who wanted it. Contrary to this position, a smaller group of experts advocated full information about both benefits and harms of breast screening. They particularly wanted consumers to be provided with understandable data about overdiagnosis, including readily comparable information on chances of mortality benefit versus overdiagnosis.

Experts' reasoning about their preferred communication approach

Experts gave a variety of reasons to explain their positions on communicating with consumers. Table 3 presents the range of reasons for experts' preferred approaches to breast screening communications. Further data, including quotations from experts that encapsulates the range of reasoning about communications, is included in Additional file 2. The major concerns of experts are discussed below.

Experts' reasoning about guidance to attend screening

Experts who preferred guidance for consumers were particularly concerned to maximise screening participation rates in order to deliver breast cancer related benefits to individuals and populations. Many also reasoned that

Table 3 Experts' rationales for their stance on guidance and information provision to women regarding breast screening

Guiding women towards breast screening
FOR
<ul style="list-style-type: none"> • Maximises screening participation^a • Saves lives^a • Women will have more treatment options^a • Overall, screening delivers more benefits than harms to the population^a • Overdiagnosis is not a harm • Providing guidance about good health is a government public health responsibility • You don't want people to make decisions in public health, you just want them to follow advice • Expecting consumers to make their own informed choice is unfair and unrealistic because the evidence is so complicated • (Some) people want to be told what to do
AGAINST
<ul style="list-style-type: none"> • Individuals should be free to make their own decisions^a • Personal autonomy is important^a • Harm:benefit ratio is equivocal so screening should be an individual choice, not a government-promoted activity^a • Screening affects only the individual concerned, so there is no community-benefit argument to justify promotion of screening • Others may not have the best interests of the individual consumer at heart • Consumers tend to be better than policy makers at remembering to consider screening harms as well as benefits, so judgements about screening should be left to consumers • The harms of breast screening are greater than the benefits
Limiting consumer information on overdiagnosis
FOR
<ul style="list-style-type: none"> • Maximises screening participation^a • Calling overdiagnosis a "harm" is just one (mis)interpretation of the facts • Women don't consider overdiagnosis a harm; main harms that women care about are: pain, hassles of parking and making appointments, radiation, breast damage, anxiety about recalls • Population based information on overdiagnosis is not applicable to individuals • The real problem is not overdiagnosis but overtreatment
AGAINST
<ul style="list-style-type: none"> • People should know what they are signing up for when they participate in screening^a • Providing information enables informed decision making^a • Informed decision making is particularly important for breast screening because there are some downsides^a • Providing full information is a professional responsibility • (Some) women want full information

^avery strongly/frequently expressed reasons

guidance was important because benefits of screening outweighed harms. Some experts added to this by asserting that overdiagnosis was not a harm, rather that the diagnosis of small cancers was exactly what the screening program was intended to do in order to reduce breast cancer mortality and morbidity. Experts also argued beyond the breast screening context, suggesting that providing advice and guidance on health matters were important public health responsibilities.

Experts who advocated against guidance were worried about overdiagnosis harms and were enthusiastic about enabling individual consumers to make their own decisions about health. They suggested that independent consumer decision making was particularly important in breast screening because of the close balance between benefits and harms, and what experts saw as the individual nature of the benefits. These experts suggested that, unlike some other public health programs, there was no community benefit associated with individual participation in breast screening: *"there is a community benefit from immunisation, but there's no such community benefit from screening. Like, the benefit is to the individual,"* (expert #8, researcher) because, *"if I choose not to go, the only person that's being harmed by my choice is me. I'm not giving the person next door to me breast cancer."* (Expert #27, researcher). They also expressed concerns that breast screening enthusiasts might not necessarily act in the best interests of individual consumers. For example, these experts suggested that governments might be driven by the promise of political gain from addressing women's health, and that providers and clinicians may have vested interests in their own employment security and remuneration.

Both groups referred to evidence-based decision making to justify their positions about guidance. Those preferring guidance suggested that individual consumers would be unable to understand the complex evidence and should therefore be provided with advice from experts about where the balance of benefits and harms lies. Those against guidance suggested that consumers, rather than experts, were better placed to use the evidence appropriately, since experts tended to ignore the harms and focus on the benefits. One expert advocated against guidance on the basis that, as they saw it, the evidence showed breast screening was likely to deliver more population harms than benefits. They believed that advising against screening was politically unacceptable, so removing guidance to screen was the next best option.

Experts' reasoning about providing information on overdiagnosis

Experts who expressed a preference for limiting information to consumers were mainly concerned about the potential impact of discussing overdiagnosis. They suggested that detailed information about overdiagnosis may result

Table 4 Experts' conceptualisation and prioritisation of values in three approaches to communication with consumers

Values	Conception of values underpinning the "Be screened" approach	Conception of values underpinning the "Be screened and here's why" approach	Conception of values underpinning the "Screening is available, please consider whether it is right for you" approach
Delivering benefits	Reduced breast cancer mortality & reduced treatment related morbidity ^a	Reduced breast cancer mortality & reduced treatment related morbidity ^a	Reduced all cause mortality and morbidity
Avoiding harm	Minimising pain, parking hassles, radiation, anxiety about false positives	Minimising pain, parking hassles, radiation, anxiety about false positives	Minimising overdiagnosis harms ^a
Delivering more benefits than harms	Experts informed by evidence to assess population benefits & harms ^a	Experts informed by evidence to assess population benefits & harms ^a	Consumers informed by evidence and personal values to assess balance of benefits & harms for themselves ^a
Respect for autonomy	Maximising consumer choices for life saving breast cancer treatment; freedom from misleading influences on consumer screening participation	Maximising consumer choices for life saving breast cancer treatment	Facilitating informed consumer decision making about screening, freedom from external (positive or negative) influences on decision making ^a
Transparency	n/a	Telling consumers what might happen when participating in screening ^a	Telling consumers what might happen when participating in screening
Professional responsibility	Providing guidance on healthy living to the population	Providing guidance on healthy living to the population	Providing full information to the population about healthy living
Respect for public preferences regarding decision-making responsibility	Consumers want to be told what to do	Consumers want to be told what to do; consumers want full information	Consumers want full information

^avalues that were prioritised for this particular communication approach

in consumers becoming confused or scared, decreasing the likelihood that they would attend screening, and reducing their options for life-saving treatment. As noted above and in Table 3, many of these experts challenged the conception of overdiagnosis as a harm, and used this to justify their support for both guidance and limited information. Importantly, these experts did not see their preference for limiting overdiagnosis information as being against informed decision making. Many of these experts were consumer advocates, and were strongly supportive of informed patient choice in relation to breast cancer treatment. They explained their apparently contradictory position on information about screening versus treatment in two ways. Some stated that the concept of overdiagnosis being a harm was based on opinion, rather than fact and therefore did not count as information. Other experts in this group suggested that maximising screening uptake would enhance patient choice (about life-saving treatments) because early knowledge of breast cancer status was an important part of this.

Experts who preferred full information argued that consumers should be informed about what they were being asked to do. In particular these experts claimed that full information on overdiagnosis was important for its instrumental role in informed consumer decision making.

Experts' reasoning was grounded in underlying values

Table 4 shows how experts prioritise and conceptualise values differently when discussing their communication

preferences. Some experts explicitly referred to values, naming principles such as "delivering benefits", "respect for autonomy" and "avoiding harms". Other experts were more concrete in their discussion, but underlying values could be readily discerned. Abstracting the experts' reasoning in this way clarifies how values were used and prioritised in association with particular communication preferences. For example, experts who advocated for "Be screened" prioritised the values of delivering benefits and delivering more benefits than harms. Those who recommended "Be screened and here's why" added transparency to this list. Experts who advocated for "Screening is available" prioritised avoiding harm, delivering more benefits than harms and respect for autonomy.

Table 4 also shows that experts conceived of or applied values differently, such that the same abstract value was sometimes used to justify opposing communication preferences. For example, although respect for autonomy was prioritised by some more than others, all experts were able to use this value to justify their preferences. Those experts who preferred "Be screened" and "Be screened and here's why" saw the provision of guidance to screen as being respectful of autonomy because it would maximise consumer choices around breast cancer treatment. Those who preferred the "Screening is available" approach suggested a no guidance agenda would better respect autonomy because it facilitated informed consumer decision making without expert or governmental influences.

Discussion

This study is, we believe, the first empirical exploration of experts' views on communicating with consumers about breast screening. We found experts considered the most important elements of this communication were the degree of guidance and the amount of information on overdiagnosis. These interacted to produce three approaches to consumer communication: "Be screened", "Be screened and here's why" or "Screening is available, please consider whether it is right for you". We expected that experts would be conversant with academic and public debates, and our study confirms that their views on breast screening communications reflect ideas being discussed in the literature [45]. The existence of controversy about breast screening is widely recognised; our results deliver both empirical confirmation and practical detail to this broad recognition.

Our study explored the reasoning and motivation of experts. Our analysis fits with and builds upon what others have suggested about the aims of screening communication. Many writers discuss what they see as the competing goals of maximising participation versus respecting consumer autonomy by facilitating informed choice about screening [29, 36, 60]. Our study explains the reasoning of experts who aim to achieve one or both goals. The detail in our study provides some insights into why debates about communication persist. We found experts disagree on what values to prioritise when considering communication strategies and have different conceptions of what it means to respect a particular value, such as autonomy, in the context of breast screening. These results validate previous, more theoretical, discussions about possible variations in use and conception of values in healthcare [16, 61, 62] and extend other research looking at experts' values in breast screening generally [52]. It is not only the values of experts that are important of course, but also the views and attitudes of the public: our study sits alongside and complements ongoing work into ascertaining public opinion about topics such as consumer communication on cancer screening [63, 64].

This study has implications for current debates about the use of ethics frameworks in public health. The Four Principles approach to medical ethics [65] is well recognised as a useful tool for assisting decision making in clinical practice and there is ongoing interest in promoting ethical care alongside or as part of evidence based medicine [66]. There is increasing recognition that the particular aims, responsibilities and challenges of public health as distinct from clinical medicine might be better served with a specific set of principles or values [67, 68]. While there is ongoing discussion about what this might look like, there seems to be broad support for some kind of values-based public health ethics framework. Our

study, however, illustrates the complexity of using such an apparently simple framework in a particular, practical context, by showing that the prioritisation and interpretation of the same values amongst influential experts is not consistent. Significantly, our results indicate that the same bare list of values could be used by different experts to potentially justify each of three very different communication approaches. In order to use values and principles to assist and steer policy, rather than "rubber stamp" existing plans, greater discussion of the meanings of values is required, situated in a concrete context (in this case, breast screening).

To support experts and others who are involved in shaping policies on communication with consumers about breast screening, we suggest the following questions as a structure to guide decision-making:

What values should drive this communication?

A wide range of values relevant to public health should be considered before deciding which one/s should be prioritised in this particular context. Those involved in discussions might start with the values that have been discussed in this paper: delivering benefits, avoiding harms, delivering more benefits than harms, respect for autonomy, transparency, professional responsibility and respect for public preferences regarding decision-making responsibility. The ethics literature suggests other values that were not raised by these experts, including distributive justice, procedural justice and trust [67–70]. Deciding which of these values to prioritise in any given context will not always be easy [68]. For the purposes of communication with consumers about breast screening, there is likely to be strong debate around the relative importance of two potentially conflicted values: delivering more benefits than harms, and respecting autonomy. Central tasks here are to agree which values are important and develop a shared understanding of what these values mean [52]. Existing public health ethics frameworks provide some guidance [67–70].

How will selected value/s be prioritised?

In order to address this question it may be useful to debate different conceptions of values and consider what communication aims would correspond with each. Note that the priority value/s are decided first, and these will help to identify and guide the stated aims of the communication. Imagine, for example, the main value is to deliver more benefits than harms. This raises the question of whether it should be experts or consumers who define which benefits and harms matter and how they are weighed. If the conclusion is that experts should decide, then the aim of communication may be to persuade consumers to act in line with expert assessment. If, in contrast, the decision is that consumers should make

their own decisions about which benefits and harms matter and how they should be weighed, then the aim of screening communication would be to encourage consumer understanding and choice.

What communication strategy corresponds to these selected aims?

It will be necessary at this point to build on answers to the questions above. For example, if it is decided that the main value is to deliver more benefits than harms, and that this is best achieved by persuading consumers to act in accordance with expert opinion, then a “Be Screened” approach would be recommended (or a “Be Screened and here’s why” approach, if transparency was also selected as an important value). However if it is decided that delivering more benefits than harms is best achieved by encouraging consumer understanding and choice then the “Screening is available, please consider whether its right for you” strategy will be selected for communicating about breast screening.

Our study’s strengths include its detail and depth of coverage through interviews with a broad range of experts from different fields and locations across the country.

We must consider that the study may be limited due to its geographic focus on Australian experts. It is likely, however, that our findings will have broader application beyond this country since the nature and detail of the breast screening program in Australia is similar to those throughout much of UK and Europe, and the values and principles discussed by the experts are well recognised worldwide. It is also possible that our findings are limited by the participating sample – that is, we must consider the question of whether or not the experts who were asked but did not participate held different views to those who did participate. Since we specifically sought to include participants from a range of professional roles and attitudes to screening, and since we continued sampling until we reached thematic saturation, we are confident that our study has mapped a sufficiently wide range of opinions and values [57].

Conclusions

This study provides the first empirical explanation of why well-informed experts take such different views on communication with consumers about breast screening. Experts do not necessarily have the same values priorities in mind, and even if they do, they do not necessarily agree on what actions would be in line with that particular value. Thus there are layers of difficulties in implementing recommended public health ethics frameworks as guidance for public health policy. We advocate for greater research into values thinking amongst public health policy makers, and would encourage explicit and ongoing discussions about what values mean and which

ones are important and why. In the meantime we provide step-by-step guidance as to how to use values in policy making within the context of breast screening in order to develop ethically robust communication strategies for consumers.

Additional files

Additional file 1: Sample interview questions. (DOC 27 kb)

Additional file 2: Figure 3 Experts’ rationales for their stance on guidance and information provision to women regarding breast screening (includes expert quotes). (DOC 82 kb)

Abbreviation

RCT: Randomised controlled trial.

Competing interests

The authors declare that they have no competing interests

Authors’ contributions

LP initiated and performed the study, and prepared the first and subsequent drafts of the paper. LR and SC assisted with study planning and data analysis, trained and supported LP in data collection and analysis methods, and made substantial contributions to draft revisions throughout. All authors read and approved the final manuscript.

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Additional file 1: Sample interview introduction and questions

Note: this list is provided as a guide only; the questions were modified to suit the experience and perspective of the interviewee.

Thank you for agreeing to participate in this study. As you know, there has been quite a lot written in the literature and in the media about breast screening and what the program should look like. Plenty of people are happy with things the way they are, but others are not. So I'm interested in exploring that range of opinion, particularly amongst people who work in the field, including those who work in clinical practice, research, administration, or in breast cancer advocacy.

- Can you describe the scope of your professional activities that involve breast screening, to give me an idea about your involvement in the program?

- Would you like to see any changes to the current program?
 - *Prompt:* What would your ideal program be?

- There are many different ideas about breast cancer screening. Can you comment on these?
 - *Prompt:* There are some who hold very extreme views about breast cancer screening. How do you respond to these ideas? What do you think drives those views?

- *(If the topic hasn't yet surfaced)* One of the topics I'm interested in is communicating with women. You may know that some places are looking at re-doing the breast screening leaflet. What are your thoughts on what should be said to women?

Additional file 2: Table 5

Table 7.5 Experts expressed a range of reasons to explain their preferred approach to breast screening communication

Guiding women towards breast screening FOR	
Maximises screening participation ^a	“The key thing is getting women in to screen and getting them there to be screened.” (Expert #31, consumer advocate)
Saves lives and means that women have more treatment options ^a	<p>“Early detection is very important in terms of the treatment options that are possible for the women. For example smaller tumours are likely to result in less invasive surgery, less radical surgery. So a lumpectomy, versus a mastectomy. Early detection is thought to be also important in survival outcomes too, but that’s obviously been a mixture of early detection plus improved treatment.” (Expert #6, consumer advocate)</p> <p>“These patients with clinically palpable lesions may then not be conservable; they may only have an option of mastectomy. They may have had an option of chemotherapy or not, whereas they’ll all be looking at chemotherapy if it’s progressed and therefore also radiotherapy.” (Expert #3, clinician)</p>
Overall screening delivers more benefits than harms to the population ^a	“The whole premise of population improvements are [<i>sic</i>] that some people are not going to benefit at all from the intervention. And so if you take a vaccine, if you take - you take anything, some people will react, you know. But on average you’re hoping to do better ... [With breast screening] look at the benefits of the intervention ... [and] the costs of it. And there is no easy ethical call on that ... By being part of this program, it accepts that some people at high risk are going to go on a more rapid trajectory for treatment, and some of them who would have just become normal get intervened upon and they have psychosocial consequences as a result of it.” (Expert #26, epidemiologist)
Overdiagnosis is not a harm	“Harm is a term that’s been developed by academics, along academic lines ... [Overdiagnosis is not] women’s definition of harm.” (Expert #24, consumer advocate)
Providing guidance about good health is a government responsibility	“By the time the governments have accepted that it’s a good thing, I think the government’s role is just to go all-out advertising it positively.” (Expert #7, clinician)
You don’t want people to make decisions in public health, you just want them to follow advice	“There’s this idea that everybody has to go through individual decision making. Whereas, see, in public health, you don’t want people to make individual decisions about washing their hands or getting their children immunised. You just want them to do it ... Now this might sound a bit extraordinary but it’s not really, for public health people.” (Expert #10, epidemiologist)

Table continued overleaf

Guiding women towards breast screening FOR <i>(continued from previous)</i>	
Expecting consumers to make their own informed choice is unfair and unrealistic because the evidence is so complicated	“When people argue a lot, you know, people that are informed, supposedly, argue, I don’t know how [women] give informed consent. It’s very difficult for the average layperson to understand.” (Expert #11, clinician) “Explaining the odds ... is hard, and you can put little figurines in this box with, so many women might, if you’re in this box, you might be there, but nothing is so black and white and everything is kind of nuanced. And it’s really hard to see people making judgements independent of what the doctor might think is the best route possible.” (Expert #26, epidemiologist)
(Some) people want to be told what to do	“Some people don’t want to be involved; some people just want to be told what to do.” (Expert #24, consumer advocate)
Guiding women towards breast screening AGAINST	
Individuals should be allowed to make their own decisions ^a	“We can’t ... be like grandparents and say, ‘You have got to do this’, and impose our will on them.” (Expert #33, clinician & provider)
Personal autonomy is important ^a	“We just, I don’t think, want to have bodies like governmental bodies or any other sorts of bodies making decisions about what people ought and ought not to be doing because it’s good for them ... I think we have to respect people’s autonomy, I think it’s a basic principal in the democracy and I think you have to respect it.” (Expert #27, epidemiologist)
Population benefits and harms are finely balanced and thus consumer attitude to risk is relevant to likelihood of delivering more benefits than harms to the individual ^a	“There’s actually a lot of evidence of harm here. If I look at it carefully, then you think, oh the benefits and the harms are much more finely balanced than I had actually appreciated, then a persuasion campaign is just indefensible.” (Expert #27, epidemiologist)
There is no community benefit or harm attached to participating in screening	“The only person who’s going to be harmed [if they don’t attend screening] is the person themselves – I mean, probably and their families because of the consequences of the treatment – but I might apply a different level of – a different sort of standard to that compared with, say, something like immunisation, where people’s decision not to be immunised affects people other than themselves.” Expert #21, epidemiologist) “If I choose not to go, the only person that’s being harmed by my choice is me. I’m not giving the person next door to me breast cancer ... whether I go or not doesn’t mean that anybody else is more or likely to get breast cancer. So I don’t think persuasion or enforcement has a role there.” (Expert #27, epidemiologist)
Others may not have the best interests of the individual consumer at heart	“You’ll get politicians like Bob Hawke who think that adding the screening program in will buy them votes ... the consultants, who are often people with vested interests, like the radiologists or the breast cancer surgeons.” (Expert #8, researcher, other)
Consumers are better at considering both benefits and harms rather than just focusing on the benefits	“At the public policy level and at that community emotive level, there is a tendency to ignore cost and harm and focus on the benefits. At the personal level ... it looks like women can [better] understand that argument about overdiagnosis.” (Expert #20, epidemiologist)

Table continued overleaf

Guiding women towards breast screening AGAINST <i>(continued from previous)</i>	
The harms of breast screening are greater than the benefits	“The evidence in Australia is that the health benefit : harm ratio is simply too high ... Opportunity costs are too high ... I would argue very strongly that [instead of breast screening] we increase our emphasis on getting women to present ... early ... and make sure that the healthcare system can diagnose disease competently in women with symptoms and treat them optimally ... My strategy for unwinding [the breast screening program] would be to stop the invitation and provide the information.” (Expert #12, clinician)
Limiting consumer information on overdiagnosis FOR	
Maximises screening participation ^a	“To give them that much information I think would scare them. They’d chuck it in the rubbish, and they’d be, like, ‘This is too hard.’” (Expert #25, provider)
Calling overdiagnosis a “harm” is just one (mis)interpretation of the facts	“[Information on overdiagnosis] is a bit of a worry, because of the way it’s presented and interpreted ... Women aren’t being harmed by breast screening and society isn’t being harmed by breast screening ... It comes from the epidemiologists, who are quite far removed from actually having breast cancer or treating it - they’re looking at populations and then they take it upon themselves ... to actually put their personal view as to what this might be doing to women, what harm it might be doing, which is very unscientific. Early diagnosis, breast screening, leads to more of your diagnoses and overtreatment and that’s [not] a harm, it’s a value... That bit of information [about the harms of overdiagnosis] is opinion interpretation... You have to be very careful what information you do give [women] and that you’re not giving them a set of facts that’s been interpreted by one kind of view.” (Expert #13, consumer advocate)
Women don’t consider overdiagnosis a harm; main harms that women care about are: pain, hassles of parking and making appointments, radiation, breast damage, anxiety about recalls	“Pain and parking, right? They were the two complaints that women had about mammograms. And also having to book.” (Expert #10, epidemiologist) “If you ask women what harm is from breast screen they’ll say, maybe, harm is the x-rays that you get. Maybe harm is the fact that you have your breast squeezed so much and that might cause damage to your breasts ... As long as you’re given the key factors ... you know, ‘We just thought this is your first time at Breast Screen, you better come back for further diagnostic images’, [so] then if you are going to be recalled then you’re not panicked.” (Expert #24, consumer advocate)
Population based information on overdiagnosis is not applicable to individuals	“I don’t think you need to put in the business about overdiagnosis ‘cause you don’t actually know that it’s overdiagnosis. Until you know which women were – that some were actually – you don’t know. It’s just not there, so I don’t think it’s very straight reasoning, to get those very big picture things and try to apply them to the individual, when you don’t know whether they could possibly apply to the individual.” (Expert #13, consumer advocate)
The real problem is not overdiagnosis but overtreatment	“I always like to think [the harm] is not necessarily overdiagnosis but overtreatment ... So don’t stop yourself from actually being diagnosed but then when you get the information, it’s what you do with it. And the patient needs to be very well informed around what your risks are if there’s no treatment versus the treatment.” (Expert #6, consumer advocate)

Table continued overleaf

Limiting consumer information on overdiagnosis AGAINST	
People should know what they are signing up for when they participate in screening ^a	“They need to be provided with adequate information to know what they are signing up for. If they are coming to screening they need to know.” (Expert #33, clinician & provider)
Providing information enables informed decision making ^a	“[We should let] women know in an intelligent way about this complex topic so that they can be fully informed and make an informed choice ... you don’t want to just say, ‘Trust me I’m a doctor.’” (Expert #22, clinician & provider)
Informed decision making is important because there are some downsides to breast screening ^a	“This is not straightforwardly a good thing. There are some downsides and, while we don’t necessarily think the downsides are such that you shouldn’t be doing it, at the very least, we should be telling women about this so that they can make an informed decision.” (Expert #20, epidemiologist)
Providing full information is a professional responsibility	“We have a responsibility for them to understand why they’re coming.” (Expert #4, clinician) “I do believe ... that people working in public health have a responsibility to talk about their work and to educate the community. I don’t think it’s something where you do the work, you publish it in an academic journal and that’s the end of it.” (Expert #21, epidemiologist)
(Some) women want full information	“People ... are different in ... their needs for information ... You have to cover the high information needs people.” (Expert #23, clinician)

NOTE: ^aVery strongly / frequently expressed reasons.

**Chapter 8: The role of socially embedded concepts in breast cancer
screening: an empirical study with Australian experts**

8.1 Chapter introduction

This chapter contains the following publication and additional online files:

Parker L, Carter S. The role of socially embedded concepts in breast cancer screening: an empirical study with Australian experts. 2016. Public Health Ethics. 2016;Apr19:phw012.

Available at:

<http://phe.oxfordjournals.org/content/early/2016/04/18/phe.phw012.short>

The Role of Socially Embedded Concepts in Breast Cancer Screening: An Empirical Study with Australian Experts

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It is not clear whether breast cancer screening is a public health intervention or an individual clinical service. The question is important because the concepts best suited for ethical reasoning in public health might be different to the concepts commonly employed in biomedical ethics. We consider it likely that breast screening has elements of a public health intervention and used an empirical ethics approach to explore this further. If breast screening has public health characteristics, it is probable that policy and practice experts will employ socially embedded concepts when reasoning about it. We gathered data on whether and how these concepts existed in the discussion and reasoning of Australian breast screening experts. We found that experts employed these concepts when talking about the purpose and practices of breast screening, and the behaviour of breast screening professionals and consumers. Experts gave varied judgements about breast screening based on reasoning with these concepts, considering it to be more or less successful in contributing to the public interest and in incorporating socially embedded concepts into its operational agenda. Our findings are compatible with breast screening having public health characteristics. We advocate for the incorporation of socially embedded concepts in breast screening policy and practice.

Introduction

The breast screening programme in Australia is government-funded and organized, and offers free biennial screening by mammography to all women from the age of 40 years. The programme aims to reduce breast cancer mortality and morbidity within Australia through early breast cancer detection via mammographic screening ([BreastScreen Australia, 2015a,b](#)). Screening providers recruit through regular, personalized written invitations that are sent to all women in the target age range of 50–74 years whose contact details are accessible through government sources (the electoral role). Breast screening is provided in fixed locations throughout urban areas and in mobile screening vans that service rural and remote communities on a regular basis. There has been recent international controversy about breast screening,

particularly around: the extent of breast cancer mortality benefit, including for younger women; the extent and significance of overdiagnosis¹ in breast screening; and the extent to which women should be informed about overdiagnosis ([Carter *et al.*, 2015b](#); [Parker *et al.*, 2015a](#)).

The Public Nature of Breast Screening

In writing about the ethics of screening, a number of writers have questioned to what extent screening should be seen as an individual enterprise—a service to individual patients for their benefit—and to what extent it should be viewed as a collective enterprise, that is, a public service designed to benefit populations ([Verweij, 2000](#); [Juth and Munthe, 2012](#)). This question is important because the sorts of concepts that are best suited for ethical reasoning in public health might be

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different to the concepts that are commonly employed in biomedical ethics (Dawson and Jennings, 2012).

Arguments to support the view that breast screening has an at least partially 'public' character are described here. First, Verweij (2000) suggests that a policy of offering breast screening to a population serves the public interest, even if only weakly. In making this argument, Verweij describes public interests in the context of preventive medicine as interests that are shared by (or common to) *all* members of the public, including those not at risk from the illness being considered (i.e. those who will not immediately benefit from an intervention). Thus, for the offer of breast screening to be regarded as in the public interest, it would have to be in the interests of everyone, not just in the interests of women. If we accept that the offer of breast screening in a population leads to reduced breast cancer mortality rate in that population, then this is likely to be true, since it is reasonable to suppose that everyone in a population benefits from a reduced breast cancer mortality rate, even if quite tangentially. However, there is only a weak public interest, for two reasons: it is unlikely that an offer of breast screening is universally in everybody's *net* interest, where net interests are determined from consideration of *all* of a person's preferences, since some individuals would quite plausibly not have their overall preferences best served by being part of a population that offers breast screening. Furthermore, if we compare an offer of breast screening against other health interventions, or even with other ways of reducing breast cancer deaths (such as better treatment), breast screening will not necessarily come out on top for all people.

Secondly, Juth and Munthe (2012) argue that screening programmes look more like social institutions, with specific internal regulations and particular societal functions and goals, than like a disconnected series of consumer-provider interactions. They argue that this means screening programmes should be considerate of collective values, such as might apply to any social group or institution with a particular agenda and mode of operation, as well being responsive to individual values. Finally, the offer and the promotion of breast screening accords with the view of Verweij and Dawson (2007) as to what constitutes 'public health', which includes (1) an aim to improve the health of the public and (2) operation through a collective (government funded) intervention.

Notwithstanding other aspects of breast screening that seem to have a clearly individual or clinical character (e.g. a personal choice to participate, the importance of outcomes to the individual) the arguments described

above present a strong case for considering that breast screening is, in some meaningful sense, unavoidably public. As noted earlier, this is likely to have implications for how we should reason about breast screening. That is, it is commonly argued that the set of concepts often applied in biomedical ethics are insufficient for reasoning about ethical challenges in the kinds of health programmes and interventions that have this 'public' character. One form of this argument is to propose that socially embedded concepts should form the basis for reasoning in public health ethics (Dawson and Jennings, 2012).

Socially Embedded Concepts in Public Health Ethics

Socially embedded concepts are associated with a particular way of looking at the world that begins with community and relationships as being of central importance. This is founded in acceptance that humans are social beings. This has been contrasted to a way of looking at the world that prioritizes the interests of individuals and assumes *prima facie* priority for liberty or respect for autonomy (Dawson, 2011; Dawson and Jennings, 2012). In the public health ethics literature, a range of concepts have been recognized as having this 'socially embedded' character including reciprocity, solidarity, trust and social justice (Upshur, 2002; Dawson, 2011; Dawson and Jennings, 2012).

Reciprocity, for example, is one concept that has been of particular interest in recent years. According to this principle, the receipt of benefit creates a moral obligation to return benefit. Empirical studies have shown that humans have a tendency to deliver benefits to, or comply with requests from those who have previously acted favourably towards us (Gouldner, 1960; Whatley *et al.*, 1999). The principle of reciprocity also applies to the spread of burdens in a society: public health ethics writers have suggested that communities have a responsibility to ensure that burdens are fairly distributed by supporting and/or compensating those who are heavily burdened or wronged in the process of acting in the public interest (Harris and Holm, 1995; University of Toronto Joint Centre for Bioethics Pandemic Ethics Working Group [JCB Working Group], 2005; Verweij, 2005; Selgelid, 2008; Viens, 2008; Viens *et al.*, 2009). Despite increasingly common usage in public health, and strong support from the social science literature for reciprocity being an important influence on societal behaviour (Whatley, *et al.*, 1999; Viens *et al.*, 2009), the details surrounding the concept may not always be

obvious. It is not clear, for example, how and by whom the value of benefits and burdens should be measured. Neither is it clear whether the nature of the reciprocal behaviour should be a positive act (such as doing a favour or shouldering a burden), a negative act (such as deliberately avoiding behaviour that may harm the other) or both (Viens, 2011). There are differing views about whether the principle of reciprocity should only apply when a benefit has been accepted or invited, or whether it should apply in all situations (Viens, 2008).

Solidarity is another example of a socially embedded concept of recent interest in the public health ethics literature. Solidarity involves identifying with the other, such that you are prepared to ‘stand beside’ them, working together towards a common or collective cause such as promoting community health and well-being (Dawson and Jennings, 2012; Ter Meulen and Wright, 2012; Jennings, 2015). It relies on the understanding of mutual vulnerability and respect between members of a community, delivering an obligation to share burdens and threats (Hayry, 2005; Prainsack and Buyx, 2011; Butler, 2012; Dawson and Verweij, 2012; Illingworth and Parmet, 2012). There are debates about whether solidarity sits as a discrete entity alongside other guiding values in public health ethics, or should instead operate as a particular perspective that sees the world as a series of enmeshed relationships, and interprets all relevant moral considerations in light of this (Dawson and Jennings, 2012; Jennings, 2015; Jennings and Dawson, 2015).

Solidarity relies upon identification with the other to drive a sense of moral obligation to act, while reciprocity relies upon awareness of the mutually beneficial system of transactional debt and repayment. The meanings of these concepts may overlap; for example, some consider that reciprocity is a constituent part of solidarity and vice versa (Houtepen and Ter Meulen, 2000; Haryry, 2005; Butler, 2012). Reciprocity, solidarity and other socially embedded concepts have their roots in public interests and the idea that community and relationships have intrinsic moral value, not merely instrumental value as a means to promote particular ends, including self-interests (Houtepen and Ter Meulen, 2000; Perugini *et al.*, 2003; Hayry, 2005).

The Role of Socially Embedded Concepts in Breast Screening

To summarize: there is recognized contention about the degree to which cancer screening can be thought of meaningfully as a public health programme. While not

negating the possibility of breast screening having a clinical or private dimension, we have argued that screening has at least some elements of a public health intervention: the availability of breast screening is in the public interest; the programme itself operates and functions like a social institution; breast screening aims to benefit the public and is supported, funded and promoted by the government. If these arguments are accepted, then concepts relevant to public health ethics are likely to be relevant to breast screening, including recently championed socially embedded concepts.

To further explore this topic, we undertook an empirical study to understand what concepts experts used when reasoning about breast screening. If our analysis of the public elements within breast screening is correct, it might be expected that experts would draw on socially embedded concepts when reasoning about breast screening. We present an analysis of the data in which they did this to expand on what has already been written about the public-ness of screening programmes, and the associated relevance of socially embedded concepts. Our research questions were as follows:

- (1) Do experts refer to, or reason with, socially embedded concepts in relation to breast screening?
- (2) If so, what forms does this take (how do they reason, what is the range of ways that experts reason with these concepts)?

In keeping with our Empirical Ethics approach (see below), we were also interested in considering the normative implications of our findings—i.e. whether or not the reasoning that occurs with references to socially embedded values is morally good.

Method

Methodology

This research was part of a larger empirical study into ethical issues in breast screening practice and policy, itself an element within a bigger project looking at ethics in cancer screening more generally. Other papers arising from the breast screening arm of the project have been published elsewhere (Parker *et al.*, 2015a,b,c). We approached our topic with a commitment to empirical bioethics, that is, on the assumption that both the practice and theory of ethics are important (Carter, 2009; Frith, 2012). More particularly, we sought empirical data about the range of ways that those people involved in influencing breast screening policy refer to socially embedded

Table 1. Characteristics of experts (Parker *et al.*, 2015a)

Participants 33 (<i>Experts who were invited but did not participate 13</i>)			
Professional role^a	Clinicians ^b 15 (3)	Oncologists 3 (1) Surgeons 4 (0) Breast physicians 1 (2) Radiologists 2 (0) Radiation oncologists 2 (0) Pathologists 3 (0) Other 0 (1)	
	Non-clinical researchers 14 (3)	Epidemiologists/biostatisticians 9 (1) Other 5 (1)	
	Administrators/managers 6 (2)	6 (2)	
	Advocacy leaders 6 (7)	Consumers working in advocacy 3 (6) Clinicians/researchers working in advocacy 3 (1)	
	Public stance on breast screening^c	Supportive 16 (9)	
		Mostly supportive ^d 3 (1)	
Critical 6 (0)			
Unknown to researchers 8 (3)			

^aNote that some experts held more than one professional role.

^bMost clinicians engaged in research to a greater or lesser extent.

^cWe loosely categorized potential interviewees as being 'supportive', 'mostly supportive' or 'critical' about breast screening based on publicly available commentary.

^dBroadly supportive of breast screening but with selected concerns about one or more elements of the programme.

concepts when talking about breast screening. We were interested in mapping all of the ways that experts reasoned with concepts about breast screening, and were also interested in experts' perceptions of how these concepts were being used and understood in a broader public setting. We assumed that the insights gained from analysis of this data might have implications for public health ethics researchers and for breast-screening policymakers and practitioners (Strong *et al.*, 2010).

We used an open qualitative methodology, with methods for sampling, data collection and analysis that were best suited to conducting our study and answering our particular questions with internal coherence (Carter and Little, 2007; Carter, 2010). Methodologically we were committed to developing new insights through inductive analysis, while being sensitized to existing ethical concepts (Mason, 2002; Charmaz, 2006). We did not set out to examine the role of socially embedded concepts in breast screening; rather, this topic was developed inductively as our work progressed as something that was important to at least some of the participants.

Participants and Sampling

We sampled the population of influential Australian breast screening experts, defining 'influential' as those who had a strong impact on public opinion or policy related to breast cancer screening by virtue of: frequent commentary or publications in lay or academic press; membership of policy advisory bodies; a senior role in breast screening administration or service delivery; or a senior role in breast screening advocacy. The population was identified through academic and media publications on breast screening, web-based personnel lists of organizations involved in breast screening and breast screening advocacy, and suggestions from colleagues and previously interviewed experts. To gain maximum variation of ideas and opinions, we used purposive sampling, inviting people with a range of experience and professional roles including clinicians, non-clinical researchers, administrators and advocacy leaders (see Table 1; Miles and Huberman, 1994).

We invited 46 experts via emails and interviewed 33 (17 male, 16 female) about the Australian breast-screening programme and breast screening generally. We had a

low response rate from volunteers in formal consumer advocacy roles. This may have been due to a higher turnover of people in these positions than in other professional roles, that is, they may no longer have been available at the publically listed email addresses we used. We continued sampling from this and all other professional roles until we were confident that we had sufficient variation in the perspectives included, and were no longer hearing new information (thematic saturation; Mason, 2002).

Data Collection

Interviews were conducted in person in the workplace of the expert or Author 1, or via telephone if the expert was interstate or otherwise unavailable. There was no observable difference between the two forms of interview technique in terms of rapport or interview length, as previously reported in the literature (Sturges and Hanrahan, 2004). All interviews were conducted by Author 1 between October 2012 and October 2013 using a semi-structured question list designed to elicit the experts' views on breast screening in general, and paying particular attention to current controversies such as overdiagnosis (Additional File 1). We did not pre-empt participants by asking direct questions about socially embedded concepts such as reciprocity or solidarity, instead we asked experts about their experience and opinions on screening and what they thought was good or bad about the programme and why. We provided experts with ample opportunities to expand upon their own perspectives in their own words and probed issues as they arose. The interviews lasted between 39 and 105 minutes (average 66 minutes) and were taped, transcribed and de-identified.

Data Analysis

Socially embedded concepts were identified as key concepts in interviewees' talk. Further data analysis was conducted through a series of iterative steps. We read transcripts closely, extracting all text that expressed concern for notions like, or aligned with, socially embedded concepts such as reciprocity or solidarity, trying to be inclusive in our data extraction. Only one expert used the word 'solidarity' and none mentioned the word 'reciprocity', but their discussion did address the kinds of concepts and related issues that our reading of the literature on socially embedded concepts had led us to understand as being relevant to these moral considerations. Clues that experts might be talking about these kinds of concepts included conversational triggers such

as *responsibility, obligation, owe, accountability, duty, if... then*, as well as more conceptual pointers. Following this, transcripts were coded to capture these values-in-use, and the codes were collapsed into more abstract categories (Additional File 2). The analyst (Author 1) then returned to the transcripts to check the validity and applicability of the categories developed, and to extract any further relevant data (Reichert, 2007). These steps were repeated as necessary. Analytic memos were written by Author 1 throughout the period of data collection and analysis and these, along with codes and categories, were shared and discussed with the other author. Some of the early interview transcripts were double coded by both authors as a cross-check on the interpretative work of Author 1. Our analysis deliberately pursued the range of variation of experts' views. Data analysis kept pace with data collection, enabling early ideas to inform and be tested during later interviews, thus maximizing the efficiency and analytic fertility of data collection. We remained critical and reflexive about our analysis, working against confirmation bias and checking our working hypotheses regularly and rigorously (Mason, 2002; Charmaz, 2006).

Research Ethics

Ethics approval was granted from the Cancer Institute NSW Population & Health Services Research Ethics Committee [HREC/12/CIPHS/46] and the University of Sydney Human Research Ethics Committee [#15245]. Informed written or verbal consent was given by all experts, and they were assured of confidentiality. Experts were free to withdraw at any time.

Results

Experts reasoned with many concepts when talking about breast screening. Much of their reasoning revolved around important individually oriented concepts, particularly (1) respect for individual autonomy; (2) the potential to deliver benefit to individual screening participants; and (3) the potential to harm individual screening participants. We have written extensively about this in other papers (Parker *et al.*, 2015a,b,c). As described above, in this sub-study we focused our analysis on experts' discussions of socially embedded concepts. We found that experts referred to and reasoned with socially embedded concepts in the following categories: the purpose of the programme, how the programme should operate, behaviour of breast screening

professionals and women's breast screening behaviour. We describe these findings below.

The Purpose of Breast Screening

Some experts talked as though socially embedded concepts were highly relevant to decision making for breast-screening policies and practices, with many of them alluding to a public interest in breast screening, or to 'the benefit that [a screening programme] will give to the society' (Expert #28, clinician). For example, one expert saw breast cancer as a cause of widespread community suffering, and understood breast screening as being at least partly an attempt to prevent suffering at the societal level:

Breast cancer is such a common illness and it touches everybody. A lot of people have someone in their family or close friends. . . everybody knows someone or there's another mother at the school or there's some story. . .there's great hope that the screening program is going to be protective in some way. (#30, clinician)

Some of the experts who discussed the public interest in breast screening saw the programme as being hugely successful in this regard. For example, one expert who looked at the 'whole impact' of breast screening on 'society and the economy' including 'the economic value of longer productive lives. . . [and the] psychosocial impact for families, friends and colleagues' judged the programme to be successful because it delivered 'a lot of value to. . . families and workplaces. . . value to the economy as well' (#32, consumer advocate).

Other experts who discussed the possible public interests of breast screening questioned the strength of the public interest argument for breast screening in comparison with other public programmes:

As a population is it our priority to reduce the burden from breast disease or is it poverty? . . . Could we actually achieve the same aims of reducing the death toll from breast cancer without spending the vast amounts of money and put money to some other use that might be of more benefit to people in general? (#28, clinician)

Some were more openly critical about the apparent failure of breast screening to address the health concerns and needs of the whole community, and suggested that such purposes might be better served through greater attention to interventions in issues such as domestic violence or disability or other public health interventions that particularly focused on the health of those

who were most needy. Overall, these experts appeared to suggest that the public were best served by attending not only to the aggregated health of a society, but also to health distribution:

It's a bad thing if there are groups in our society that are left behind in terms of their health. A civilised society needs to think about the health of each population. (#22, epidemiologist)

The Process of Breast Screening

Several experts appeared to reason about or judge certain breast-screening policies by referring to socially embedded concepts, particularly the principle of reciprocity, with participants linking burdens of breast screening with (reciprocal) moral obligations of the programme. For example, some experts suggested that breast screening required higher standards than might be expected from a clinical healthcare perspective in relation to aspects such as certainty of evidence, operational and evaluation excellence and avoidance of harm. According to these experts, 'the bar has to be higher' (#21, researcher) because the screening programme was being paid for out of the 'public purse' (#3, clinician) and because, like other public health endeavours, it requested the participation of healthy individuals, delivering a burden of consideration on consumers who were otherwise well:

A screening program is taking people that are well as opposed to people that are unwell, going and seeking medical attention. And therefore you've got a greater obligation to do it properly. (#9, clinician)

One expert raised the issue of possible compensation to those who carried the heaviest burdens, recommending monetary remuneration to those who were likely to have been overdiagnosed:

Say, every woman who was diagnosed by Breast Screen with a breast cancer under 1 cm in diameter—can't be felt—who is alive and disease free at 3 years, would be compensated \$100,000 because there is a 15:1 chance they didn't need treatment. (#31, clinician)

Experts saw some breast screening policies as being (wrongly) focussed on breast screening consumers to the apparent exclusion of the needs or interests of the wider community, including women with breast cancer. They spoke about the separate financial arrangements for mammography screening and follow-up in Australia that facilitated free, high-quality screening

mammograms for women without breast cancer, while women with breast cancer were required to pay for their follow-up mammograms, and/or (allegedly) had access only to inferior equipment, or no access at all. In other locations, they described a policy of physical separation between women without breast cancer and women with breast cancer attending mammography services for screening and cancer follow-up, respectively. One expert explained that ‘you can’t mix a woman who’s got breast cancer with a woman who doesn’t have breast cancer’ (#29, clinician) and another provided the allegedly official reason: ‘It could be a negative impact on normal women because they would be afraid to have their screening because they [would] associate it with breast cancer and death and dying and stuff.’ (#5, clinician). Experts expressed moral disapproval for the ‘inward looking culture’ (#29, clinician) in breast screening that allowed for this apparent lack of interest in members of the public beyond the immediate breast screening consumers.

The Behaviour of Breast Screening Professionals

Experts applied socially embedded concepts to the behaviour of themselves or other breast screening professionals. Some experts spoke with moral censure about ‘a lot of fighting’ (#9, clinician) amongst screening providers, rather than a co-ordinated process of working together towards a common goal. Others described co-operative work, but towards a goal that failed to serve the public interest:

It’s look after themselves. . . that’s what I saw. . . All they cared about was their jobs, their promotions, their money, their salaries. (#29, clinician)

Other experts appeared to see themselves as being personally involved in and morally bound by reciprocal transactions within their breast screening activities. For example, one expert spoke about the duty of health-care professionals to provide personal guidance and advice about breast screening, as opposed to devolving responsibility to the consumer, an obligation that was at least partly incurred because of being a beneficiary of medical university training (university degrees in Australia are financially subsidized by the federal government):

It’s really hard to see people making judgements independent of what the doctor might think is the best route possible. . . Why did we pay this person so many taxpayers’ money to go through a degree? (#15, epidemiologist)

Another expert discussed obligations arising within the research community, speaking disparagingly about experts who worked with figures generated by the research activities of others, without ever generating their own primary data, thus failing to pay off their apparently incurred debt:

[The other side] have done no trials, zero. They’ve milked the data from the breast screening trials and not got ethical clearance for their own particular viewpoint. They’ve not won any grant money for that. They’ve not conducted population based studies with long follow-up, and they’ve piggy backed off someone else’s research. (#3, clinician)

Finally, we noted that experts talked at length about the multiple collective benefits relating to the management of breast cancer that they considered had arisen as a direct result of the introduction of organized breast screening in Australia and extended over and above any breast cancer mortality or morbidity benefits derived by individual women as a result of being screened:

The current program. . . has [had] a lot of beneficial effects. . . over many years, particularly in raising the bar for treatment of all breast cancers, whether screen detected or symptomatic. So no doubt the screening program has contributed a lot to the better care of patients with breast cancer, however they are diagnosed because it has made people work in multi-disciplinary teams. It’s made us audit what we do, collect our results, all of those things which would never have happened without it. (#12, clinician)

Other experts spoke about how organized breast screening enabled surgical and radiological sub-specialization in breast work and the beneficial legacy of that. Experts did not voice any debt arising from receipt of these benefits, but their presence raises the possibility that experts may feel some kind of obligation to continue supporting breast screening, an obligation that might remain even as the evidence about the balance of benefits and harms becomes more uncertain.

The Breast Screening Behaviour of Women

Experts recognized that women saw themselves, and were seen by others, as being under a certain degree of moral obligation to participate in breast screening and having a sense that not participating in screening was somehow wrong:

[Screening is] something that women guilt themselves into doing. (#2, researcher)

They described such obligations as coming from collective values such as solidarity. For example, one expert suggested that the public (incorrectly) saw breast screening as having a community benefit akin to the community benefit associated with vaccination programmes, and that this meant that women felt an obligation to contribute to that benefit via participation in screening:

The way that it's put forward by screening programs makes it seem like that, that this is the right thing to do rather than it's a personal decision about whether you should do this for your own good or not... There is a community benefit from immunisation, but there's no such community benefit from screening. Like, the benefit is to the individual and yet we almost make it a moral issue and people perceive this, that if they're not screening they're... a bad person in some way. (#21, researcher)

Another expert noted that some women felt a moral obligation to attend screening to preserve healthcare services for the community, inspired by a strong sense of solidarity with others. These consumers perceived that government-funded services would be withdrawn from small communities if they were not supported by public participation, and that this would be a bad outcome for those communities:

I [know] women... who'd said, 'I don't think I'll ever get breast cancer. I don't think I'm at risk of breast cancer. I'm not scared about getting breast cancer. But if I don't use this service and people like me don't use this service, the [breast screening] bus might not come back again and that will, that affects people in my community'... So it's about loss of services... And people in small communities are connected. (#8, researcher)

These experts felt disturbed by such feelings of societal obligation in women because they thought they were based on faulty assumptions about screening, or were unreasonably large burdens for women to be carrying.

Discussion

In this article, we have sought to explore the place of socially embedded concepts in breast screening. It seems reasonable to assume that socially embedded concepts are relevant to public health, not least because, as Dawson (2011) argues, there are many public health policies that seem vitally important and morally good that would not be easily defensible with a traditional biomedical ethics approach that uncompromisingly

prioritizes individual liberty. There is, however, debate over the extent to which breast screening should be considered a public health endeavour or a clinical intervention aimed at serving individual interests. We argued in our introduction that breast screening has enough 'public' characteristics to justify a claim that socially embedded concepts are relevant. For example, it has been suggested that having a breast screening programme lies in the public interest, even if only weakly; breast screening programmes appear to function as a social institution; and, in Australia at least, breast screening is a collective action, publically organized, funded and promoted, with the aim of improving the population's health.

Interviewees in this study used socially embedded concepts in a variety of ways when reasoning about breast cancer. Some experts used them to judge the success or moral worth of breast screening on the basis of its contribution to the public interest. Others used these concepts to judge or justify particular aspects of breast screening policy and practice, morally evaluate the behaviour of breast screening clinicians and researchers and consider women's breast screening behaviour.

In the following section, we draw on the literature to normatively evaluate these uses and consider whether and how might they support breast screening being seen as a public, rather than a private or clinical, intervention.

Normative Implications of this Study

Is the offer of breast screening in the public interest?

We drew earlier on Verweij's argument that a public interest is one in which 'all persons *as members of the public* have a common interest in' (2000: 61, Verweij's italics). In the context of breast screening, it would be valid to say that it is in the public interest if we could reasonably agree that everyone, including those not at risk of getting breast cancer, have an interest in the programme being available. In the introduction, we gave reasons for at least weak support for this claim. Informants in this study echoed this, emphasizing breast cancer is common within the community, and suggesting that preventing breast cancer deaths will deliver economic and psychosocial value to a community which is over and above the benefit for the at-risk individual.

There are, however, counter-arguments to this view. For example, as other interviewees argued, there may well be much stronger public interests in other

healthcare programmes, which are unable to be realized if money continues to be channelled into an expensive breast screening programme. According to this view, the claim that there is a public interest in breast screening is only true if breast screening is compared against nothing. It may become untrue if compared against an offer of other public health programmes in which there is a stronger public interest (Verweij, 2000). Furthermore, recent recognition of overdiagnosis in breast screening, the rate of which remains highly contentious, has led to the possibility that an offer of breast screening in a population will deliver an increase in population breast cancer morbidity even as it delivers a modest decrease in population breast cancer mortality. If this is true, it is much less clear that all at-risk women would share a (common) interest in the offer of breast screening, let alone the wider public. That is, it is not at all clear that an offer of breast screening is in the public interest.

The institutional model of breast screening

Juth and Munthe (2012) emphasize a different kind of ‘publicness’ for screening programmes. They propose that screening programmes are institutions. This institutional character suggests socially embedded concepts are relevant to internal practices as well as to the programme’s overall role in society. Our findings support this claim. Some interviewees certainly saw breast screening programmes as having an institutional character: operating with a degree of autonomy and internal cohesion, having specific aims, functions and key players (consumers and providers). They used socially embedded concepts to judge these internal operations and practices of screening and its key players. They also applied socially embedded concepts to the programme’s role in society, highlighting that breast screening might act in a manner that is contradictory to the public interest as defined above. While one useful contribution of the institutional model to an understanding of the ethics of cancer screening might be in the way that it highlights the application of ethics to both internal operations and to external functions of the screening programme, we were concerned about the possible implications of this model for judging the behaviour of consumers. That is, such a model might appear to reduce consumers to the role of pawns in a complicated societal institution with defined goals. We discuss this in greater detail below. We note, however, that Juth and Munthe (2012) perceive their institutional model as complementary to, rather than a replacement for, public health and medical (healthcare) ethics, and a combined approach would be likely to limit any tendency to judge the behaviour of

consumers according to their contribution to institutional goals.

Are socially embedded concepts relevant to how breast screening is delivered?

Notwithstanding all of the above (i.e. regardless of whether or not an offer of breast screening is in the public interest, and whether or not the institutional model is useful or sufficient), given that a breast screening programme exists, the other elements of publicness in breast screening that we described in the Introduction would seem to provide enough justification for a claim that socially embedded concepts have some relevance to the way that breast screening is delivered. Participants in our study appeared to agree with this, making judgements about aspects of breast screening delivery based on concepts such as reciprocity and solidarity. The use of socially embedded concepts in this context provides a new perspective on breast screening, illuminating topics and issues that are seldom explored in breast screening but seem worthy of closer inspection.

For example, if we accept that the concept of reciprocity has relevance in breast screening, it follows that the programme should consider the issue of support or compensation for those who carry the most burdens, such as overdiagnosis. In particular, policy decision makers might consider the extent to which government promotion of screening to individual women should mean that the government has some kind of reciprocal responsibility to those women for the outcome if they participate (albeit limited by the inherent uncertainties in screening). In such a scenario, the idea of support for those who carry the heaviest burdens seems reasonable; this may or may not include financial compensation or alternatives such as restitutions or reparation (Viens *et al.*, 2009). If governments adopt an approach that is more in line with enabling women to exercise informed choice about breast screening, then the programme may move closer to being a clinical intervention than a public health intervention, and the role of socially embedded concepts such as reciprocity would be less clear.

Is women’s participation in breast screening in the public interest?

In his discussion of the public interests in breast screening, Verweij argues that a (weak) public interest in having a policy to offer breast screening does not imply any public interest in actual participation by any particular woman, since ‘the decision of the individual woman not to participate in screening does not affect the potential benefits for, and hence the common

interests of other women' (2000: 59). However, the literature suggests that some women feel morally obliged to attend screening to benefit others (for example, see Willis, 2004), and we found that experts in our study also recognized this. In the introduction, we suggested that there may be no clear public interest in the participation of individual women in breast screening, and here we elaborate on that point.

First, there is no breast screening equivalent to 'herd immunity' from vaccination, whereby individual participation delivers some protection to the collective in the form of reduced risk of disease: the screening participation of an individual woman will not decrease the likelihood that other women will get breast cancer. Secondly, there is no clear basis for an argument that participation in breast screening helps to keep services cost-effective and by extension, open. Like many other cancer-screening programmes, breast screening has low set-up costs and high running costs, meaning that the cost per screen is unlikely to significantly decrease with high participation rates (Torgerson and Donaldson, 1994; Howard *et al.*, 2005). It is possible that at least some level of participation is necessary to maintain political support and funding for breast screening services, and to maintain professional expertise in identification and investigation of abnormal screening results. However, this is speculative, and may be more of an issue in rural and remote communities where absolute numbers are lower and critical thresholds more easily reached.

Finally, we consider that argument alluded to by one participant that there might be a public interest in having women participate in breast screening because this will (allegedly) enable them to live longer and thus deliver more economic and psycho-social benefits to others. There is debate about the extent to which participation in breast screening delivers all-cause mortality benefits to a community: there are suggestions that the reduced breast cancer population mortality rate associated with a breast screening programme might be at least partially offset by an increase in all-cause mortality because of a higher breast cancer incidence from overdiagnosis and the treatment-related mortality ramifications of that. Particularly given the marginal and contested mortality benefits of breast screening, the suggestion that women should participate in breast screening because they have a moral obligation to the public to remain alive seems very weak. This could readily be extended into an obligation to participate in any kind of intervention that might lengthen life, which would quickly become oppressive to individual women.

We are left, then, with two weak arguments about breast screening participation being in the public interest: (1) based on a pragmatic recognition that breast screening services require at least some (minimal) use to remain viable; (2) based on the contribution that a woman's continued existence brings to community flourishing. According to Verweij's (2000) model, weak public interests are likely to disappear when the net benefits to individuals are considered, or when the intervention under scrutiny is compared against alternatives and we suggest that either of these can do the job. First, given that there are considerable personal costs associated with participating in breast screening (anxiety, pain, the possibility of a false positive diagnosis, or more seriously, an overdiagnosis and the sequelae of that), we cannot assume that participation in breast screening is in every woman's net interests. For example, a woman's preference to avoid a breast cancer death may be at least partially matched by a preference to avoid an unnecessary breast cancer diagnosis, and given that the likelihood of the latter is a more likely outcome of screening participation than the former, it may not be in her net interests to screen. Secondly, if we compare the public interest in having an individual woman participate in screening with the public interest in having an individual woman feeling empowered to make decisions about screening that are based upon her own personal (informed) preferences it can be concluded that the latter public interest is stronger, because this means that women feel they are of intrinsic value, not simply valued for what they contribute to others.

We conclude that there is little or no public interest served by women's individual participation in breast screening. Furthermore, we suggest that breast screening providers should be open about the extent to which an individual woman's participation does or doesn't serve the public interest: it would seem wrong to be aware that women participate in screening for reasons that are spurious or invalid without at least discussing and attempting to correct them.

Implications for Researchers

This study highlights some ethically relevant issues in breast screening that have not, to our knowledge, been well covered in the public health ethics literature. For example, socially embedded concepts appear to be important in driving the process of public health interventions, but their application is rarely discussed in detail (one notable exception is 'Stand on Guard for Thee' by the JCB Working Group, 2005). It might be useful for healthcare workers if public health ethics researchers

Table 2. Specific questions to guide considerations and discussions about socially embedded concepts in breast screening policy

To what extent is the offer of breast screening in the public interest?

To what extent is the promotion of breast screening in the public interest?

What are the burdens and harms attached to the breast screening programme? Suggestions include:

- Demands on public attention
- Increased anxiety about breast cancer suffering and death
- Burden of decision-making
- Financial burdens
- Physical and emotional morbidity of screening participation and sequelae
- Screening-related mortality

What might be the reciprocal obligations incurred by the breast screening programme as a result of delivering these burdens and harms? Suggestions include:

- Ongoing efforts to measure and reduce burdens
- Consideration of alternative, less burdensome ways to achieve aims of the programme (and deliver similar benefits?)
- Consider ways to support and/or compensate those who carry the heaviest burdens

Consider the impact of breast screening policies and practices on solidaric connections between people, including:

- Key players in breast screening (such as consumers, providers)
 - The general public (including breast screening consumers, breast cancer patients, others)
-

provided practical guidance about the use of socially embedded values in the process of breast screening—Table 2 provides an example of what this might look like in practice.

In addition, the contribution of ethics researchers to specific public health interventions might be enriched by not only exploring arguments about the public interest in participation, but by comparing theoretical reasoning with empirical evidence about consumer motivation to participate. As in breast screening, it may be that there is a mismatch between what researchers suggest about the strength of the public interest in participation and what consumers perceive to be their moral obligation to participate to contribute to others. Exploring and explaining this might be helpful for consumers.

Implications for Policymakers and Practitioners

As discussed above, socially embedded concepts are at least relevant at the process level in how breast screening is delivered, and policymakers and practitioners should therefore consider these concepts when talking about policies and practices. They might benefit from education and support in the use of these concepts. Table 2 describes one possible framework for guiding these kinds of discussions. In addition, policymakers and

practitioners should be aware of the arguments for and against a public interest in screening participation, and take care that their policies and practices reflect valid messages in this regard.

Finally, one unexpected finding in our studies was the hint that some of our participants might feel a sense of obligation to the programme itself because of benefits that had been delivered in relation to breast cancer management and to auditing practices for screening. If policymakers and practitioners are indeed strongly influenced by the principle of reciprocity in this manner, they might be supporting breast screening programmes to a greater extent than would be warranted by the evidence. However, we note that while the benefits discussed by these interviewees have already been delivered, it may be that there are more of these type of benefits that breast screening programmes might deliver in the future, or that the continued existence of the programme will at least support their maintenance. For example, quality control of screening mammography might plausibly remain higher with the continuation of an organized, government-sponsored programme containing a built-in auditing process, compared with a purely opportunistic programme that does not have any centralized quality assurance programme. As such, for those women who have a net interest in participating in breast screening, an organized breast-screening

programme might be preferable to an opportunistic programme. This is a complex issue, worthy of further research, and largely beyond the scope of this article except insofar as to suggest that policymakers and practitioners should be alert to the possibility of their own sense of moral obligation to the programme, and consider the strengths and weaknesses of such an attitude.

Strengths, Limitations and Future Research

As with any inductive analysis, we had to guard against circularity in our arguments: that is, we were careful not to define socially embedded concepts in particular ways that fitted our data. Instead, we were sensitized to the various meanings of socially embedded concepts in the literature and while purposefully looking for any text that expressed any ideas similar to these we also sought diversity in our data and looked for counter-examples. We closely examined each element of data that suggested experts were using socially embedded concepts, deliberately testing for compatibility with other, more individually orientated concepts and being clear about levels of uncertainty in our results.

Our study benefits from in-depth analysis of attitudes and values amongst experts from a range of backgrounds and experience. However, it is focused on a particular situation—breast screening—so may not be transferable to other contexts. The results suggest that at least some experts refer to socially embedded concepts in breast screening. It is possible that we have not captured the full range of the ways that experts reason with these concepts. Although we sought to maximize diversity of views and ideas amongst the participants, there may have been some concepts that were not discussed during our interviews, and it is possible that the experts who agreed to take part were somehow different from those who did not. We are confident, however, that our efforts to conduct extensive interviews and include participants with a range of backgrounds and differing opinions about breast screening has minimized such possibilities. We have not sought, in this study, to explore the views of women or members of the broader public. This would be an important area for future research.

Conclusion

We set out to examine whether and how expert policymakers used socially embedded concepts to reason about breast screening using an Empirical Ethics approach. Our empirical findings suggested that at least some experts employ socially embedded concepts when talking about breast screening. Experts reasoned with these

concepts in relation to the purpose of breast screening, the way that it is delivered, and the behaviour of breast screening professionals and consumers. Experts drew a variety of conclusions, judging the breast screening programme to be very or not very successful in serving the public interest, and in the inclusion of socially embedded concepts such as reciprocity and solidarity into its operational agenda. They censored colleagues who appeared not to be acting in accordance with socially embedded concepts, and acknowledged that these concepts might produce a sense of moral obligation to participate in breast screening in some women.

Our empirical findings are compatible with the claim that breast screening has at least some elements of a public health intervention. We advocate for consideration of socially embedded concepts in relation to the purpose and internal operations of breast screening. We also suggest that those who formulate breast screening policies and practices should be aware of the moral obligations that drive some women's breast screening behaviour, and take care with what messages they are sending in this regard.

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Supplementary Data

Supplementary data are available at *ESR* online.

Notes

1. For the purposes of this study we defined overdiagnosis as the screening diagnosis of a breast cancer that would not otherwise have come to symptomatic or clinical attention during the woman's lifetime, and where the diagnosis does not deliver any benefit to the woman (Carter *et al.*, 2015a).

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Additional file 1: Sample interview introduction and questions

Note: this list is provided as a guide only; the questions were modified to suit the experience and perspective of the interviewee.

Thank you for agreeing to participate in this study. As you know, there has been quite a lot written in the literature and in the media about breast screening and what the program should look like. Plenty of people are happy with things the way they are, but others are not. So I'm interested in exploring that range of opinion, particularly amongst people who work in the field, including those who work in clinical practice, research, administration, or in breast cancer advocacy.

- Can you describe the scope of your professional activities that involve breast screening, to give me an idea about your involvement in the program?

- Would you like to see any changes to the current program?
 - *Prompt:* What would your ideal program be?

- There are many different ideas about breast cancer screening. Can you comment on these?
 - *Prompt:* There are some who hold very extreme views about breast cancer screening. How do you respond to these ideas? What do you think drives those views?

- *(If the topic hasn't yet surfaced)* One of the topics I'm interested in is communicating with women. You may know that some places are looking at re-doing the breast screening leaflet. What are your thoughts on what should be said to women?

- *(If the topic hasn't yet surfaced)* Recent studies suggest that some cancers found at screening would never have come to clinical attention in that person's lifetime. What are your thoughts on this issue?

Additional file 2: Sample codes and categories

Examples of codes used for analysing interview data.

- Views on screening
 - Overall thoughts on breast cancer screening
 - What is important about breast cancer screening
 - How own views are formed
 - Harms including how to balance harms and benefits
 - Changes would like to see / ideal program
 - Justification for suggesting those changes or having stated views
 - Why own view is right
- Evidence & more
 - What evidence is accepted or used as right (numbers, names)
 - Why that evidence used e.g. what are the influences on self regarding interpretation of evidence
 - General ideas about evidence
- Views of other people
 - Comments on different / contradictory evidence
 - Comments on possible influences on other people / why they think the way they do

Examples of categories used for analysing interview data

- What does the state owe women?
- What do women owe the state?

- What do experts owe each other?
- What do experts owe women / the state?
- Breast screening – women assisting women
- Breast screening – community interests
- Experts working together
- Community interests vs. individual interests

Chapter 9: Discussion and Conclusion

9.1 Chapter Introduction

This study began with the observation that there were substantial disagreements about breast screening among many leading experts in the field. People who are intelligent, apparently well-meaning, and familiar with the evidence, seem to arrive at different conclusions regarding the right thing to do in breast screening policy and practice. I set out to explore the reasons behind this conflict and make suggestions for constructive progress, with particular emphasis on the role of values. I found that breast screening experts held different values and that these values appeared to underpin their views on breast screening. I discovered that values were conceptualised and prioritised in a range of ways, but that as values were rarely discussed, there was ample potential for miscommunication and seemingly irresolvable conflict about what was considered important in breast screening. I concluded that people involved in influencing or directing breast screening policies and practices might benefit from information, further education, and opportunities to think and talk about values in a structured way. This might include teaching and learning activities to promote greater familiarity with the language and concepts of ethics, explicit encouragement of personal reflection around values, and regular discussion of values in the context of breast cancer screening. In order to improve understanding among experts about each others' views, and to assist in consensus building, it would seem useful to formally include discussions about ethics in decision-making processes for breast screening policies and practices.

9.2 Conflict in breast screening

Disagreements about evidence

Many writers and journal editors have acknowledged the controversy about breast screening and the often-polarised nature of expert opinion.¹⁻⁶ Concerns about self-interest and commercial matters aside,⁷⁻¹⁰ the cause of disagreement amongst well-meaning experts has been frequently attributed to disagreements about the evidence. Certainly the vast amount of breast screening evidence includes many conflicting results and interpretations. There are numerous plausible explanations about why this might occur. For example, the particular evidence that experts construct or consider as most important to read and use, will vary depending on their epistemic preferences^{11, 12} as I discussed in **Chapters 5** and **6**. It may be influenced to a greater or lesser extent by cognitive biases that affect human judgement generally, including wish bias (the tendency to interpret evidence that supports what one wishes to hear), confirmation bias (the tendency to seek out or interpret evidence that reinforces existing views),^{7, 13, 14} or availability bias (the process of judging importance or frequency by the ease with which examples come to mind).¹⁵ Such biases can help explain some of the patterned links between experts' professional roles and opinions about breast screening that I described in **Chapters 6** and **7**. Experts' interpretation of the evidence will also be influenced by the extent to which their thinking conforms to the biomedical paradigms I described in **Chapters 1** and **2**, including assumptions about the natural history of breast cancer and the use of technology in medicine.^{7, 10, 11, 16} Furthermore, the views of experts are likely to be shaped by the wider social and political factors I discussed in **Chapter 2**. For example, experts – like all people - are vulnerable to the framing effect of

widely used relative risk formats for reporting risk reduction associated with breast screening, which may lead them to overestimate the benefits of breast screening.¹⁷

Disagreements about values

While these factors help to explain at least some of the expert disagreements about breast screening, they do not reveal the full story. That is, even when experts agree about the evidence they may still disagree about one or more aspect of breast screening.^{2, 9, 11, 18}

Decisions in healthcare depend not only on analysis of the evidence but also on what is valued in relation to that evidence.¹⁹ Thus, for example, it is not enough to have information about outcomes and the processes of achieving those outcomes: there must also be a set of values that shapes what is considered good or bad about those outcomes and processes.

Disagreements about values are therefore likely to be another important factor behind disagreement amongst breast screening experts. The influence of values on the views of breast screening experts has been acknowledged, but not, until now, systematically or empirically studied. One of the major contributions of my research has been to provide empirical detail about how experts' values influence their perspectives on breast screening.

In **Chapter 5** I have described wide variation in how experts conceptualise and prioritise relevant values, and the ways in which this influences their views on breast screening in general. In **Chapters 6** and **7** I have drawn out the relationship between the values that experts hold and their views about the particular topics of overdiagnosis and communication with consumers. In **Chapter 8** I described experts' discussions around socially embedded values and discussed their relevance to breast screening.

This detailed picture of the ways in which values influence experts' views about breast screening provides a solid base for understanding some of the ongoing controversies. For example, disagreements about the significance of overdiagnosis may be at least partly to do with conceptualisation and prioritisation of “avoiding harm” (See **Chapter 6**). Similarly, much of the disagreement about what is communicated to consumers about breast screening may be underpinned by variation in conceptualisation and prioritisation of “respect for autonomy” (See **Chapter 7**). This thesis provides knowledge and understanding about experts' values and the roles they play in shaping experts' views and disagreements, an ideal position from which to begin examining how best to guide policy and practice decision making, particularly around contentious issues.

9.3 How to proceed in the face of conflict in breast screening

Throughout the empirical papers in this thesis, I have not only described the range and variation of experts' values, I have also drawn on that information to make suggestions for constructive debate and decision making regarding breast screening policy and practice, even in the face of ongoing expert disagreement. The remainder of this chapter draws on and extends these discussions.

Addressing conflict requires identifying and then considering the sources of disagreement.²⁰ I have noted above how the role of evidence in the conflict has been well discussed and described, and how the role of values has been noted, but until now, not considered in any detail. There have also been a number of suggestions about what, if anything, to do about breast screening controversies. I describe here two main approaches from the existing

literature, concentrating on evidence and values respectively, and then add my own new interpretations and recommendations.

Evidence

Many proposed solutions to breast screening conflict have focused on the evidence, and involve the presentation of a particular set of epistemological preferences or claims about how others should construct or use evidence. For example, there have been calls to ignore certain swathes of the published literature on breast screening as being “faulty science”,^{21p107} beset by epidemiological inadequacies such as “the use of incomplete data”,²² “grave errors”^{23p206} and “inappropriate analyses”.^{3p82} These strongly worded recommendations suggest that the authors have deeply held and opposing ideas about what evidence is acceptable evidence. This was supported by my empirical research, which showed that experts gave very different accounts of what constituted sufficient and good quality evidence (**Chapter 5**). A slightly different approach has been to encourage clearer communication of the results of research^{8, 24, 25} together with better education of experts, and subsequently the public, in topics relevant to the interpretation of breast screening evidence. This has included proposals to improve general numeracy, encourage understanding of epidemiological principles including uncertainties, limitations and harms in screening, and to raise and explain the concept of non-progressive breast lesions.^{16, 17, 26} Efforts to reduce the impact of wish or confirmation bias (as well as the influence of vested financial or professional interests) have resulted in greater emphasis on independence in analysis of the evidence.^{7, 9, 25,}

Values

Others who seek to resolve breast screening conflict have focused on addressing values, suggesting that at least one reason for disagreement about breast screening is that experts hold different perspectives on what is important.^{9,28} While acknowledging the role of evidence as discussed above, my study has concentrated predominantly on this latter approach, testing the ideas that values are important in breast screening decision making, and that differences in values might contribute to conflict. My empirical findings confirmed the importance of values in decision making for breast screening policy and practice. I found that breast screening experts do talk about values and describe their moral reasoning processes when discussing their views on breast screening (See **Chapters 5 to 8**), and that values appear to inform and underpin much of their thinking, including around contentious topics such as overdiagnosis and communication with consumers (See **Chapters 6 and 7**). Furthermore, my results confirmed that there is variation in the ways that breast screening experts conceptualise values. For example, the concept of respecting autonomy was interpreted and actioned in a variety of ways by experts, ranging from breast screening support and advocacy, to endorsing a stronger focus on informed decision making in breast screening (**Chapter 5**). I also found differences in the sorts of values that were held to be most important. For example, some experts appeared to focus more firmly on delivering benefit, while others were particularly concerned about avoiding harm (**Chapter 5**). The ways that experts conceptualised values and perceived their relative importance was linked to different views about breast screening. There has been discussion in the literature about addressing conflict in breast screening by concentrating on the differences in people's values. Suggestions have included: removal of values from decision making, promotion of one or

other value as a priority, and open discussion about values. I will describe these ideas in turn, outlining their strengths and weaknesses, before describing my own recommendations.

Some have proposed that since differences in the way people think about values allegedly lie at the heart of breast screening conflict, values should be excluded from decision making.

They argue for a so-called “objective” interpretation of “raw evidence”,^{29p956} implying that this would yield a value-free view of breast screening, and would resolve disagreement.

Others contend that it is unrealistic and unhelpful to suggest that values can be removed from decision making.^{18,30} They see evidence as vital in answering questions about breast screening policy and practice but, since those questions are fundamentally driven by what it is that society considers to be important, it is values, rather than “massed files of scientific evidence”^{18p310} that lie at the heart of decision making.

Other writers have suggested solutions that rest heavily upon one or more value that they appear to see as being particularly important, without discussing the strengths or weakness of competing values in any depth. For example, some who write about overdiagnosis in breast screening allude to an apparent conflict between the ethical concepts of maximising benefit and respecting autonomy, and justify their recommendation to promote informed choice by simply assuming and stating that the latter is the dominant value.³¹⁻³³ Those who continue to support opposing practices, such as strong guidance and recommendations in favour of screening, cite a different value to justify their position (maximising benefit), either ignoring the values prioritised by others or appearing to believe that their position self-evidently trumps alternatives.³⁴ Arguably, presenting one particular value as an unassailable ‘trump card’ in this way leads to success for those with the loudest or most influential voice rather

than what is most ethically correct, or to a stalemate position with experts unwilling to be persuaded of alternative points of view.

Less frequently, writers have attempted to approach contested issues in breast screening by identifying values that appear to be in conflict with each other within the given context, and encouraging debate about which value is more important, and why.²⁸ It seems important and useful to promote deeper ethical reflection and discussion about an issue, as this may lead to decisions that are more ethically sound, and more in keeping with what we actually hold to be important in life than decisions made without such a considered moral foundation.^{35,36}

Disappointingly however, these efforts have generally stalled at the outset. My empirical results provide some clues as to why this might be so (see **Chapters 5 to 8**). Firstly, some experts may reject the idea that values are relevant or should be included in decision making. Secondly, experts may conceptualise values differently, which may result in people using the same terminology with quite different meanings, and thus failing to successfully communicate.

My recommended approach

My recommendation for addressing conflict is to include values-based discussions at all levels of breast screening policy debate and decision making, advice that is supported by my empirically derived explanations of how values may influence different positions and perspectives. Thus I suggest that discussions about values should be included, along with discussions about evidence, at times of policy set-up, evaluation, and review, as well as during times of controversy and decisional conflict. This would require the participation of all stakeholders in a clear endorsement of the role of values, nuanced understanding of the

plurality of views, and reflective discussion of different ways in which values are conceptualised and prioritised.

My approach builds upon suggestions described above, and also upon more general discussions and guidance about incorporating values into evidence-based healthcare decision making. This includes the GRADE framework for evaluating evidence as part of the process for producing evidence-based guidelines, which incorporates assessments of values regarding benefits and harms, in particular, the extent to which intervention outcomes are generally regarded as being desirable or undesirable.³⁷ GRADE authors recommend that decision-making panels should use the perspective of patients when thinking about benefits and harms,³⁸ and should be transparent about their estimates or assumptions regarding these typical patient values.^{39, 40} The GRADE framework is widely endorsed, although the (limited) empirical evidence about its usability and effectiveness suggests there may be room for improvement,⁴¹⁻⁴³ especially in the field of public health where benefits and harms may be both more complex, and an insufficient reflection of relevant ethical considerations.⁴⁴ Other writers have encouraged those drafting or reviewing healthcare guidelines and policies to include discussion of a range of their own personal values in decision making processes, citing theoretical justifications such as the improvement of transparency, predictability, accountability, legitimacy and appropriateness of recommendations.⁴⁵⁻⁴⁷ These authors do more than simply promote a generic list of ethical principles for decision makers to consider, rather they call for those involved to discuss relevant ethical concepts and to be open about their values, explaining what ethical issues are most important and most influential for their decisions in the given context and why. My approach builds on these ideas, and does so in a manner informed by my empirical findings. In this way, it is specifically adapted to the

breast screening scenario. Aspects of my approach have been described in **Chapters 5 to 8**, and I have collated and synthesised those discussions below.

1: Acknowledge the role of values

My empirical findings that some experts dismissed or ignored values leads me to recommend including explicit acknowledgement of the role of values at all levels of policy decision making. In this way, my approach builds on the work of those who argue that the role of values in breast screening decision making should be acknowledged, and that the inevitable values differences should be anticipated.^{7, 11, 18, 20, 30, 48} Thus I agree with Ransohoff and colleagues, who call upon the key players in the breast screening debate to “agree at the outset that informed judgments are an essential part of decision making, whether by individuals or by society, and that differences in judgments should be expected and respected”.^{49p1033} Experts should be encouraged to see values as being relevant to breast screening decision making; achieving agreement on this point may require active support and further education for experts.

2: Develop knowledge and skills in ethics: education and self-reflection

Ethics education is common practice in clinical training programs, and increasingly advocated in public health training.^{35,50} Curiously, however, knowledge of relevant ethical issues is rarely a pre-requisite for participation in policymaking processes. Given the centrality of values and ethical concepts to the policymaking process revealed in this study, it seems likely that training in ethics, including in vocabulary, basic concepts, and skills for

critical self-reflection, would assist those charged with designing programs to deal with the challenges of their task.

I did not set out to test the extent to which experts possessed ethics knowledge, or skills in self-reflection, but my empirical results leads me to expect that ethics education for experts will be of benefit. For example, my finding that experts held differing interpretations of values, and did not necessarily recognise this (see **Chapter 5**) indicates that experts who do mention ethical concepts may often be talking at cross-purposes. Increasing experts' awareness about the possibility of variation in the meanings that others may attach to particular values or concepts is an important step towards reducing misunderstandings. Similarly, my empirical observation that some experts openly rejected the notion of ethical consideration (see **Chapter 5**) suggests that at least some decision makers might have limited experience in self-contemplation of the range of factors that shape their own views about what is important in breast screening and why. Encouragement and training in self-reflection is valuable because it seems probable that it will provide a more solid foundation for decision-making in a given context (e.g. breast screening policy and practice). That is, while policy makers are certainly capable of making decisions about ethically-relevant issues without formal ethics training, arguably personal judgements made without the assistance of a developed capacity for careful moral reflection will be less enduring and less coherent than decisions made after deep consideration about one's own values.³⁶

3: Regular discussions about values

Considered discussions about ethical aspects of healthcare seem likely to deliver more ethically appropriate decisions.³⁵ For example, group deliberation on moral aspects of a

given topic would arguably increase the likelihood that decision makers would identify a broader range of relevant viewpoints, and recognise possible biases in their own preliminary conclusions. In addition, the process of discussing values regularly should provide more opportunity for those involved in decision making to address any values-based conflict that does emerge in the future.

There are many possible ways to structure discussions about values. I have used my empirical findings to inform two possible models or frameworks for how this might occur, details of which are provided below. These suggestions can be used together or separately. They might benefit from fine-tuning after practical testing and evaluation, and are not necessarily the only processes for incorporating ethics discussions into breast screening decision making.

Model 1 – Incorporating values into policy aims and evaluation

In **Chapter 7** I suggested that discussions about values in breast screening should include debate around a list of relevant values to develop an understanding of what each value means, and make decisions about which values are most important in the given context. In this section I provide further detail on how this discussion model might be structured.

In the early stages of my research I drafted a list of ethical values likely to be relevant for decision making in breast screening policy (**Table 4.1**, reproduced here and re-labelled as **Table 9.1**).

Table 9.1 Ethical considerations relevant to decision making for breast screening policy and practice. (Draft version)

<ul style="list-style-type: none">• Maximise health benefits• Minimise harms• Deliver more benefits than harms• Deliver the most benefit possible within the resources available• Respect autonomy• Maintain transparency, including communicating honestly• Distribute benefits and burdens justly• Uphold reciprocal obligations• Act in solidarity with others

SOURCE: Reproduced from Chapter 2

I have since drawn on my empirical work and theoretical analysis of the literature to make adjustments to the list categories and to include detailed annotations for each item (see **Table 9.2**), developing what was a simple inventory of values into a decision-making tool with step-by-step guidance in the form of specific triggers and questions for discussion (**Table 9.2**).

Decision makers can use this annotated table by working through the four sets of discussion triggers. The first trigger set encourages decision makers to consider the relevant values for their own particular breast screening context; a suggested list is provided and discussants can add any additional values as they wish. The second set of triggers relates to the range of conceptualisations of each value in the context of breast screening: each discussant can describe their own conceptualisations and the group can draw on evidence such as the papers contained within this thesis to identify others. The third set of triggers is intended to stimulate debate about the strengths and weakness of each conceptualisation, and to encourage consideration of which one or more might be the most relevant for the given breast screening context. Again, the group may need to draw on epidemiological and other evidence to provide supporting information. The fourth and final set of triggers is about the priority level of each value in the given context. Decision makers are asked to consider

competing values and discuss the implications of this. Discussants will need to draw heavily on the evidence for knowledge about processes and about the extent and certainty of specific outcomes from breast screening, in order to meaningfully compare things that are held to be important in this field.

(see table on following pages)

Table 9.2 Framework to guide decision making in breast screening policy and practice (annotated version)

Range of conceptualisations for each relevant value	Notes on strengths or weaknesses of a given conceptualisation	Questions (and evidence) to consider when debating the relative importance of each relevant value
Maximising health benefits <i>(See Chapters 5, 7 and 8 for more detail)</i>		
Reducing population mortality rate from breast cancer and/or all causes.	It may be unreasonable to expect to obtain evidence of all-cause mortality reduction associated with breast cancer screening because of the large numbers of research participants that would be required. A disease-specific (i.e. breast cancer) mortality rate is more amenable to empirical study than an all-cause mortality rate, although arguably the former may not provide a complete picture: i.e. may miss mortality implications of overdiagnosis.	How much, and what kind of health benefit accrues from breast screening, and how certain is the evidence about this?
Reducing population breast cancer morbidity by enabling less aggressive breast cancer treatment for individuals.	Any apparent reduction in treatment-related morbidity as a result of breast screening may be offset by the increased morbidity associated with overdiagnosis.	
Providing relief from breast cancer related anxiety.	This apparent benefit may be artificial: reduced anxiety after a negative screen may partly derive from previously inflated anxiety due to screening promotion.	To what extent is anxiety about breast cancer inflated by a breast screening program and related promotional activities?
Improving the overall health of the entire population.	While the availability of breast screening might offer benefits to a population, it also: delivers harms, is an expensive program with high opportunity costs, and arguably fails to address the main health needs of those with the poorest health outcomes.	To what extent do efforts to maximise the health benefits of breast screening impinge on other relevant values, e.g. by delivering harms, consuming financial resources, maintaining or increasing health inequalities?

Table continued overleaf

Minimising harms (See Chapters 5, 6, 7 and 8 for more detail)		
Monitoring and/or ensuring a low occurrence rate in one or more of the following outcomes: overdiagnosis; overtreatment; false positive test; false negative test; radiation damage; personal financial burden.	Measurement uncertainty in some conceptualisations of harm (e.g. overdiagnosis) is high in comparison to measurement uncertainty in common conceptualisations of benefit, making it difficult to interpret the significance of such harms. In addition, the degree of personal suffering related to a given conceptualisation of harm (e.g. overdiagnosis, overtreatment) may be highly variable. Despite this, ignoring certain harms because of measurement uncertainty or variability in suffering would seem to be an unreasonable exclusion of morally relevant considerations.	How often do each of these outcomes occur in any given breast screening program and how certain is the evidence about this? Who should decide how significant these harms are in comparison to benefits? Given that breast screening is largely initiated by health services and offered to well women, ⁵¹ and that harms may accrue to individuals who receive no benefit, to what extent are practitioners responsible for minimising harms in breast screening compared to, for example, clinical interventions provided in response to requests from those who are sick and where benefits and harms accrue to the same individual?
Avoiding an excessive increase in societal and/or individual anxiety about breast cancer suffering and death.	A certain level of health-related anxiety may be considered useful rather than detrimental to an individual and a society, acting as a stimulus to public health interventions and personal behaviour that lead towards better health. Arguably however, anxiety about breast cancer is currently exaggerated well beyond what seems in keeping with what is known about its incidence, and impact on morbidity and mortality, and may be considered harmful.	To what extent does the offer and promotion of breast screening result in breast cancer related anxiety?
Avoiding an excessive burden of decision making for women in regard to the consideration of breast screening participation.	Breast screening experts cannot agree about whether or not women should participate in breast screening, suggesting that there is no obviously correct decision for a consumer.	To what extent, if any, do women consider decision making about participation in breast screening to be burdensome? If so, how might this burden be reduced while still enabling and encouraging women to be informed and involved in making decisions about participating in breast screening?
Paying close attention to quality control in breast screening services	Arguably the cost of quality control programs must be reasonable.	To what extent would efforts to maintain high quality services increase screening provider costs?

Table continued overleaf

Delivering more benefits than harms <i>(See Chapters 5, 6, 7 and 8 for more detail)</i>		
Ensuring that breast screening reflects experts' considered decisions on how to design the program so that resulting population health benefits outweigh population harms.	Where benefits and harms are finely balanced, as in breast screening, it seems reasonable to encourage greater individual consideration about participation than might normally be expected in public health interventions.	To what extent are the views of individuals and the public important in determining the balance of benefits and harms in breast screening?
Ensuring that women make an informed choice about breast screening participation, incorporating their personal views on benefits and harms.		
Ensuring, and regularly reassessing whether or not breast screening is, overall, in the public interest.	Arguably a calculation about whether breast screening delivers more benefits than harms requires consideration of not only the direct outcomes of the program but also indirect factors that affect population health, such as: the financial and opportunity costs of the program, and its impact on health inequalities (see notes above on "delivering benefit").	How, and by whom, should calculations be made about whether or not breast screening is in the public interest?
Maintaining cost-efficiency <i>(See Chapter 5 for more detail)</i>		
Ensuring that the financial cost of avoiding one breast cancer death is comparable to the cost of other similarly effective healthcare interventions.	Arguably the up-front cost of avoiding one death because of a public health intervention is not readily comparable to the up-front cost of saving one life from a clinical healthcare intervention: preventing ill health may deliver more benefits to society than treating sick individuals (because the latter may experience long periods of lower productivity prior to their healthcare intervention).	How does the financial cost of avoiding one death or saving one life as a result of breast screening compare with other healthcare interventions?
Maintaining a minimum breast screening participation rate of around 70% in order to keep the cost-per-screen as low as possible.	The main financial costs associated with breast screening relate to running costs rather than fixed costs, and therefore the cost-per-screen is relatively static once an initial (very low) base participation rate is reached.	In what way are breast screening participation rates linked to cost-efficiency?
Minimising administrative inefficiencies associated with the breast screening program.	This would appear to be an important aspect of public health service delivery.	Are there any unnecessary inefficiencies in the administrative aspects of breast screening?

Table continued overleaf

Respecting, supporting or enhancing autonomy (See Chapters 5, 6 and 7 for more detail)		
Ensuring that women are not coerced into participating in breast screening.	There are strong drivers of breast screening that funnel a woman towards a particular “choice” in favour of participation. This may be exacerbated by promotional activities from sources such as providers and advocacy organisations. Arguably however, participation in screening does not necessarily accord with what the woman would choose after considered, informed reflection.	To what extent do promotional activities result in a woman’s breast screening choices differing from what they would be after a more contemplative and informed decision making process?
Providing relevant information and opportunities for women to make an informed choice about participating in breast screening (including informing about harms).	The possibility that an informed choice process will allow women to make an autonomous choice about breast screening might be limited by difficulties in consumer understanding of information that is complex and conflicts with long standing public health beliefs (such as the concept that early diagnosis is always important). That is, achieving informed decision making might be time-consuming and expensive, resulting in heavy burdens for the individual and the community.	How much would it cost to facilitate informed decision making for breast screening participation? What is the best way to facilitate informed decision making amongst breast screening consumers with minimal burden?
	Notwithstanding the comments in the cell above, encouraging consumers to engage in informed decision making about breast screening might reduce participation rates, thereby possibly reducing benefits.	Would the encouragement and facilitation of informed consumer decision making reduce breast screening participation rates? If so, to what extent does this matter?
Increasing available options for effective treatment (by providing the opportunity to access less aggressive, earlier treatment)	While some women who participate in screening will have increased treatment options, many more women will have their lives constrained by the impact of outcomes such as false positive results and overdiagnosis.	What are the likely outcomes for an individual woman from participating in breast screening?
Providing ready access to breast screening for all women, including those younger and older than the target age range.	The likelihood that a woman’s options will be constrained rather than enhanced by breast screening is even more likely for younger women and older women with significant co-morbidities, because the benefit to harm ratio of breast screening is reduced in these population sub-groups.	What are the likely outcomes for younger and older women? To what extent is it reasonable for providers to limit access to breast screening, in order to protect the best interests of individuals?
	While healthcare choice is important it must arguably be balanced against cost-efficiency: allowing unrestricted access to breast screening might increase costs without improving population health.	To what extent is it reasonable for providers to limit access to breast screening, in order to contain costs?

Table continued overleaf

Distributing benefits and harms in a just manner <i>(See Chapter 5 for more detail)</i>		
Ensuring that all women in the target screening population have an equal opportunity to participate in, and be informed about, breast screening.	While equality of opportunity is important it must arguably be balanced against cost-efficiency.	What are the financial costs of interventions to encourage breast screening in hard-to-reach groups? To what extent would it be reasonable to incur these costs in order to pursue fair distribution of breast screening access and information?
Having an even distribution of breast screening participation rates across the population.	Setting a target for equality of participation across different population groups might be an important tool to facilitate fairness, but has the potential to lead to coercive promotional techniques aimed at sub-groups with low rates of screening participation.	See notes and questions above on whether or not promotional activities are coercive.
Facilitating an even distribution of breast cancer mortality, or overall health, across the population.	Including a population health focus that incorporates issues of health inequality may appear to be a very broad agenda, but arguably is within the remit of all public health interventions. Breast cancer is relatively evenly spread across the population (slightly more common in women of higher socio-economic backgrounds) and arguably communities would be better served by interventions that concentrated on improving the health for those with the poorest health outcomes.	To what extent, if any, will a population offer of breast screening affect health inequality across that population?
Communicating honestly <i>(See Chapters 2, 5, 6 and 7 for more detail)</i>		
Providing relevant information about the harms of breast screening to consumers and the general public.	While providing information about the harms of breast screening might reduce participation rates, thereby possibly reducing benefits, honest communication between healthcare providers and the public would seem to be a central tenet of our healthcare system.	What information needs to be provided to women in order to maintain honesty in communication?
	Notwithstanding the comments in the cell above, public disclosure about overdiagnosis will need to be managed carefully and sensitively: some people may become distressed upon receiving the information that they may have been overdiagnosed and there may be reduced public confidence in the healthcare system.	How can information about overdiagnosis in the breast screening program be communicated to the public in such a way as to minimise individual distress and maintain public trust and confidence in the healthcare system.

Table continued overleaf

Communicating honestly <i>(continued from previous)</i>		
Using independent experts to provide information to women to assist them in making an informed choice about breast screening participation.	The common practice of requesting breast screening units to meet high participation targets and also to write information pamphlets for consumers might well be, or be seen to be, a conflict of interest. It would seem sensible to either remove participation targets, or use independent writers for consumer leaflets, or both.	Are there any independent writers that can be called upon to provide information for women? What would be the impact on breast screening rates of removing participation targets?
Making policy decisions with a fair, honest, and transparent process <i>(See Chapters 2 and 5 for more detail)</i>		
Using independent experts to review the evidence and/or make policy decisions.	Those with professional or financial conflicts of interest in breast screening might be influenced, or be seen to be influenced, by matters other than the best interests of women and communities when involved in decision making for policy and practice.	Are there any independent experts that can be called upon to make decisions about breast screening policy and practice and if so, how can independent experts ensure that their decisions about breast screening are sufficiently grounded in the realities of breast screening?
Ensuring that policy decision-makers disclose any conflicts of interest.	The problems of conflict of interest described above might persist even if conflicts of interests are disclosed.	
Ensuring that all relevant stakeholders, including clinical experts, have an opportunity to participate in decisions about breast screening policy.	Despite the above comments about conflict of interest, it would seem useful to allow stakeholders input into breast screening policymaking. (Stakeholders may be a rich source of important and relevant information; allowing stakeholder input may help to build useful alliances and increase decision-making legitimacy)	How should the views and relevant experiences of stakeholders be obtained and communicated to decision makers for breast screening policy and practice?
Publicly disclosing the values used to guide breast screening policy and practice; possibly involving the public to decide on these values.	Given that decisions about breast screening policy and practice present many ethical challenges and tensions, it seems important that the public are informed about the kinds of values that guide decision-making bodies. Arguably it is also important for policymakers to seek out the values and views of informed members of the public e.g. through deliberative democracy methods such as a citizens' jury.	How should the values and views of an informed public be obtained and communicated to decision makers? To what extent would this information influence decision makers to select different breast screening policies? To what extent is this relevant? (i.e. To what extent do inclusive, democratic processes for policy making have intrinsic value independent of their outcomes?)

Table continued overleaf

Upholding the reciprocal obligations (of government and public health providers to members of the public) <i>(See Chapter 8 for more detail)</i>		
Maintaining efforts to measure and reduce population burdens, harms and costs associated with breast screening.	The burdens, harms and costs of breast screening could possibly be reduced through modifications to the screening program (e.g. variable screening guidelines for specific target populations, and/or use of new technologies).	What would be the outcomes and implications (e.g. for individual choice) of different breast screening guidelines and technologies? To what extent should individuals be allowed to choose how and when to screen?
Considering other, less burdensome and/or less expensive ways to reduce population breast cancer mortality and morbidity.	Breast screening carries significant opportunity costs, and at least some of the expertise, time and money directed at breast screening could arguably be more effective if used elsewhere (e.g. on research to improve breast cancer prognosis and treatment).	What is the likelihood of being better able to reduce the burden of breast cancer through means other than screening (e.g. prevention or treatment)?
Supporting those who are most burdened by breast screening (e.g. those likely to have been overdiagnosed).	The nature of overdiagnosis means that it is currently very difficult, or impossible, to identify those people who have been most heavily burdened by breast screening, although it still seems morally important to try.	How could the individuals who have been most heavily burdened by breast screening be identified and what would be the best way to support those individuals?
	There may be concerns about the implications (e.g. legal and financial) of acknowledging and identifying those who carry particularly heavy burdens related to breast screening. Arguably however, such concerns must be weighed against the importance of upholding reciprocal obligations.	To what extent would the provision of support for these individuals reduce the cost-efficiency of breast screening, and how important is this?
Respecting and facilitating solidaric connections <i>(See Chapter 8 for more detail)</i>		
Including considerations of community interests when making decisions about breast screening policy and practice.	Community interests and well-being appear to be less frequently discussed in the breast screening context than individual interests, but are arguably of considerable moral significance for this public health intervention.	To what extent, if any, is the offer and promotion of breast screening in the public interest?
Ensuring that women with breast cancer have similar healthcare access and support to women in screening.	There may be good reasons for public health and clinical interventions to be funded separately, but it seems morally important that this does not create artificial divisions between people (e.g. breast screening consumers vs breast cancer patients).	How can we ensure that women attending breast cancer treatment services are not disadvantaged compared with women attending breast cancer screening services?

Table continued overleaf

Respecting and facilitating solidaric connections <i>(continued from previous)</i>		
Encouraging women to see participation in breast screening as a moral obligation to others.	A woman's feeling of moral obligation to participate in screening in order to retain services for others seems morally problematic. That is, notwithstanding the importance of community solidarity, it would seem an unreasonably large burden to expect individual women to carry.	To what extent, if any, does a woman's participation in breast screening benefit others? If so, how much burden is it reasonable to expect her to carry in order to benefit others?

Decision makers who prefer a less prescriptive decision-making tool could use the following template version (**Table 9.3**), which presents the set of triggers without accompanying notes or specific questions.

Table 9.3 Framework to guide decision making in breast screening policy and practice (template version)

Draft a list of the relevant ethical values
e.g. consider: maximising benefit; minimising harms; delivering more benefits than harms; maintaining cost-efficiency; respecting autonomy; distributing benefits and harms in a just manner; communicating honestly; making policy decisions with a fair, honest, and transparent process; upholding reciprocal obligations; respecting and facilitating solidaric connections
List common conceptualisations of each value
Consider the strengths and weaknesses of each conceptualisation
Consider the relative importance of each value
e.g. To what extent would interventions aimed at addressing any given value compromise other relevant values because of the required processes or the likely outcomes? If significant conflict between values is likely, how should this be resolved?

NOTE: Discussants might need to draw on or commission evidence to assist with these questions

The framework does not proscribe an outcome or provide a neat solution for all breast screening controversies. It does, however, act as a guide for how to discuss and identify important concepts in breast screening, and how to incorporate both values and evidence in decision making, in a cohesive manner. It might also assist with identifying important unknowns: areas of research need in the context of breast screening.

Model 2 – Structured discussions around frames to address contentious issues

In **Chapter 6**, I described a model that might be used to guide values based discussions in the context of a particularly contentious topic such as overdiagnosis. In this model, experts were guided to use framing theory to explore a range of ways that a given problematic issue might be viewed. As described in **Chapter 6**, a frame consists of the set of ideas around the issue, incorporating factors such as: what the problem is, what the relevant information consists of,

and a related moral judgement. Together these factors point towards a particular solution. There can be several different frames for a given issue, and any individual might use one or more frame, often unconsciously, when thinking and talking about that topic.

Decision makers in breast screening policy and practice might find that some issues remain contentious and difficult to resolve, despite receiving support and training in the use of values, and despite regular discussions about values aided by the framework presented above. In such a situation, it might be useful for decision makers to bolster the more abstract discussion about values that the framework encourages with a very contextual, situated discussion about the different ways that are used to frame a contentious issue, and the extent to which any one of these frames with its internal moral judgement is reasonable and acceptable. As described in **Chapter 6**, this kind of discussion might allow decision makers to achieve deeper understanding for the positions and values of others, and may enable greater appreciation of commonalities or similarities in thinking. In addition, talking through a range of solutions and where they stem from might facilitate problem solving, including identification of likely areas for negotiation and compromise. Thus I suggest Model 2, structured discussions around frames, as a method for addressing aspects of breast screening where ethical concerns appear particularly prominent and are seemingly irresolvable. I would recommend that decision makers incorporate the guidance from Model 1 into their regular decision making processes, and use Model 2 as an adjunct for particular issues, as and when necessary. Model 2 can also be used on its own for those decision-making bodies who are unable or unwilling to follow the guidance of Model 1.

The process of structuring discussions around frames begins with achieving a general appreciation of what frames are; decision makers may benefit from support and training in this. Decision makers are then encouraged to draw on their own views and, if necessary, evidence about the views of others, to complete a tabled set of frames about the topic under review. An example of such a set is provided in **Chapter 6 (Table 2)**, where the topic in question is overdiagnosis. A second example is provided in this chapter (see **Table 9.4**) and relates to the contentious issue of communication with breast screening consumers. (I have used the data from **Chapter 7** along with information on social pressures from **Chapter 3** to inform **Table 9.4**. I have annotated the table with notes to assist decision makers in this topic.) The final step is for decision makers to use their completed table to stimulate discussion, considering whether or not they agree with each of the various factors underpinning each frame and why, and contemplating the range of solutions.

(see table overleaf)

Table 9.4 Possible frames relating to communicating with consumers

Frame	Defining the problem	The reasons for the problem	Value judgement	Proposed or implied solution	Notes (strength or weakness of this frame)
Informed decision making is vital.	Women are currently unable to make an informed decision about breast screening participation.	Breast screening providers do not provide adequate information about harms. Providers are conflicted because of participation targets.	Women should have the opportunity to make an informed choice about breast screening participation and this requires a realistic understanding of breast screening harms. Information should be written by independent bodies and/or participation targets should be scrapped.	Provide more information about screening harms; use independent bodies to provide information to consumers about breast screening; encourage informed decision making e.g. through distribution of decision aids or training of primary care practitioners.	Informed decision making might be very difficult to achieve, given the complexity of the evidence and the long history of alternative messages (such as “early diagnosis is vital”).
Guidance is important.	All this talk of harms is putting women’s lives and breasts at risk.	Detailed information about harms is likely to deter women from breast screening.	Public health programs should provide guidance to women about breast screening participation according to what they consider is likely to be in the best interests of all women. A woman’s interests are best served by keeping her alive, and be increasing her options for effective breast cancer treatments (i.e. through earlier diagnosis).	Continue to guide women towards participating in breast screening.	Screening participation may not be in the best interests of an individual woman. This may be particularly relevant for women whose chances of benefit are smaller than others (e.g. younger women, older women with co-morbidities).

Table continued overleaf

Frame	Defining the problem	The reasons for the problem	Value judgement	Proposed or implied solution	Notes (strength or weakness of this frame)
The communication preferences of individual women are important.	Women's breast screening communication preferences are not being met.	Some women prefer to make informed, independent decisions about breast screening participation, others prefer experts to guide them, and some women prefer both information and guidance.	Breast screening providers should cater to women's preferences about how much information and guidance they wish, and how much involvement they want in decision making about participation.	Provide basic information and guidance to all women and make more detailed information about harms and benefits of breast screening available upon request	Women may be unaware of the harms of breast screening, and hence not seek out the information or informed decision making opportunities that they would otherwise appreciate.
Communication to facilitate informed decision making is not a substitute for responsible policies about screening.	Facilitating informed decision making will not necessarily result in women making decision about breast screening participation that are in their own best interests.	Women are more enthusiastic about screening than is warranted because of strong social and institutional pressures to screen.	While choices about breast screening are important, public health providers also have a responsibility to protect the health of women.	Experts should facilitate informed decision making, but also set clear limits around screening opportunities in accordance with the best interests of individual women.	Screening providers should also consider the interests of the community when setting limits around screening opportunities.

Involving the public

Throughout my published papers, and in **Table 9.2**, I have noted that experts' discussions and decisions may be guided to a greater or lesser extent by the values of the public. I am not suggesting that the values of the public should necessarily drive policy in a direct manner: this may not be possible for cost reasons, and it may not be desirable - for example, the public may be ill-informed about the topic, or the values of the majority may fail to accommodate minority interests. However, it would seem important to ascertain the values of the public when making decisions about public health interventions that use public finances and reasonable to at least consider taking them into account to some degree, because the public perspective provides additional and relevant information, and because involving the public improves decision-making legitimacy.

One way to include the values of the public is to facilitate or promote individual informed decision making about breast screening participation. This approach involves enabling or encouraging women to consider the benefits and harms of participating in screening, and to make personal decisions about their actions based upon how strongly they value the various possible outcomes, rather than expecting women to unthinkingly follow population-based guidance from public health providers. This has the advantage of getting individual input about breast screening from the women who are most immediately affected by it, but there is limited scope for input from women or the broader public into how and to whom breast screening might be offered.

There are several ways of facilitating public input at the level of policy. Consumer representation on decision-making bodies is one widely used method and individual

consumers can build up expertise and knowledge about breast screening through personal or professional experience and through long participation in the field. A limitation of this method is that individual representatives may not necessarily present a view that matches the ideas of the broader public. For example, it may be that many people who participate as formal consumer representatives are also consumer advocates for a particular policy; for example, most consumer representatives in breast screening may be motivated by personal enthusiasm towards breast screening and therefore tend to present just one partisan set of views and values about the program.⁵² My empirical results suggested this possibility, since all (three) consumer experts that I interviewed expressed remarkably similar views and values in relation to breast screening (**Chapter 5**). It may be, however, that the consumers who agreed to take part in my research were more strongly committed to advocacy than other consumer representatives.

Another option is to garner the views of the public through direct polling. This method may also be problematic: breast screening is a complex topic and not always accurately presented in the media or other information sources commonly used by the public.^{53, 54} Moreover, people's views about breast screening are subject to possible vested interests of corporations, and may not necessarily receive a balanced picture of the available evidence.⁵⁴⁻⁵⁶ As such, the public may be incompletely informed about breast screening and their views might not accurately reflect their values (see **Chapter 2**).

An alternative approach to gaining the views of the public is via a deliberative democracy process, something that has been gaining increasing attention in recent years. This involves working with a small group of people from the public, providing them with relevant

information and education, and then seeking their (informed) opinions. Several types of deliberative techniques have been developed; citizens' juries are one of the most popular methods⁵² and have been convened to consider controversial topics in screening including breast screening.^{57, 58} While such an approach is expensive, and its usefulness is somewhat dependent on the skill of the convenors, if done well it can provide rich information from a broad cross section of the informed public.^{8, 52, 58} There is ample scope for further research into how best to ascertain the values of the public, and how to facilitate public input into decision making for breast screening policy and practice.

9.4 Limitations of the research

I have discussed the limitations of my research in my empirical papers (**Chapters 5 to 8**), and I expand upon that information here. The qualitative methods used in my empirical study provided rich detail relating to my research aims, but as with all qualitative work, my findings were contextually bounded, and I cannot be sure that I have described a complete picture of all the potential ways that values may influence experts' views on breast screening. It is possible that some breast screening experts conceive and use values differently from the range that I have presented in this thesis. However, I adopted strategies to seek and identify all of the most relevant and important ways of thinking. I deliberately selected participants with a range of professional experience and geographic locations, and I continued sampling until I was certain that I was no longer hearing new information.⁵⁹ I have already noted my difficulty with recruiting participants from the group of breast screening consumer advocates, and discussed how this was overcome (see **Chapter 4**).

This study was conceived and carried out in the Australian breast screening context, and as such, has direct relevance to that context. It may not be as relevant to decision making for breast screening practices and policies elsewhere. However, the breast screening debates and disagreements are conducted in an international setting, and there are many reasons for my work to resonate with other developed countries. The impact of breast cancer on population mortality and morbidity in other developed countries, especially those adopting a Western diet and lifestyle, is similar to that in Australia.^{60,61} Breast screening programs in developed countries have comparable aims and protocols to BreastScreen Australia,^{61,62} and many have analogous government endorsement and funding for breast screening.⁶³ Experts in other developed and Westernised countries are likely to consider and reason about values in a comparable manner to their Australian counterparts.

9.5 How this thesis meets its aims

As reported in Chapter Four, my research aims were to:

1. Identify and analyse the values held by Australian decision makers in relation to breast screening policy and practice.
2. Identify the aspects of the breast screening program that are particularly ethically salient and analyse those in detail.
3. Describe how to incorporate ethical considerations in order to make the best decisions for future breast screening policy and practice.

These aims are addressed in detail below.

Aim 1: Identify and analyse the values held by Australian decision makers in relation to breast screening policy and practice.

Very few participants discussed values in explicit terms but my analysis of their talk revealed that experts used ethically relevant concepts to underpin their views and reasoning about breast screening. In **Chapters 5 to 8**, I presented the range of values that experts used and noted those that were frequently endorsed or discussed. I described a plurality of ways that experts conceptualise the same values. Some values, including “delivering benefits”, “avoiding harms”, and “respecting autonomy”, appeared particularly vulnerable to divergent conceptualisations. I also described variation in how experts prioritised values, and provided a model explaining how an expert’s perception of the relative importance of values might be linked with their views about breast screening. For example, I explained in **Chapter 6** that an expert who prioritises “avoiding harm” over “delivering benefit” is more likely to view overdiagnosis as a problem requiring an urgent solution than an expert who holds “delivering benefit” to be the most important value for the breast screening program.

Aim 2: Identify the aspects of the breast screening program that are particularly ethically salient and analyse those in detail.

From my empirical work and my reading of the literature I identified overdiagnosis, communication with consumers, and the public health vs individual clinical service nature of breast screening as aspects of the program that contain particularly visible ethical concerns. I looked for combinations and patterns amongst experts’ expressed views about these issues, and presented multi-faceted but cohesive analyses of the role of ethical considerations. For example, in **Chapter 6** I discussed six different ways that Australian experts framed

overdiagnosis, and described the sorts of values that were prioritised. In **Chapter 7** I discussed and explained three different ways that Australian experts viewed communication with breast screening consumers, describing and explaining the ethical elements within each view in detail. In **Chapter 8** I identified the ways in which experts appeared to view and judge breast screening as if at least part of its role was the pursuit of population health and community interests. I drew on theoretical arguments to analyse the extent to which the kinds of socially embedded concepts that experts used were applicable to breast screening.

Aim 3: Describe how to incorporate ethical considerations in order to make the best decisions for future breast screening policy and practice.

I used my empirical research and theoretical reading to identify potential problems with the ways that ethical considerations are currently used – or not used – in decision making for breast screening policy and practice. For example, earlier in this chapter I described the limitations of using a narrowly evidence-based approach to decision making, and the need for widespread engagement and endorsement of values-based discussions and decisions.

However I also acknowledged the apparent difficulties with incorporating values based reasoning into decision making: in my empirical papers (**Chapters 5 to 8**) I described the potential misunderstandings that may occur when experts have different interpretations of a given value, and reported on the seeming impossibility of achieving progress with decision making when experts held strongly divergent views about which values were more important than others. The material in this chapter represents my efforts to determine how best to incorporate ethical considerations into future breast screening decisions about policy and practice. I end with a call for further research: to explore the usefulness of the different decision making models that I have presented; to identify the values of an informed public:

and to consider how and to what extent these values should be incorporated into breast screening policymaking.

9.6 Conclusions

Breast screening is a major public health intervention practiced throughout much of the developed world. After several decades of organised breast screening, experts continue to disagree about aspects of breast screening policy and practice. There is particularly strong debate about issues such as: how much benefit, if any, breast screening delivers, and to whom; the extent of overdiagnosis; and the meaning and importance of informed consent. Disputes over these and other contested areas of breast screening feature regularly in the academic literature, frequently involving renowned and respected experts with strongly opposing views. Conflicts spill over into the public domain, including politicians and the media, and leaving many consumers angry and confused. This research is the first comprehensive, empirical study into the role that values play in experts' views about breast screening. By analysing the ways that experts use values when they talk about breast screening, I have been able to develop tools to help identify and address any underlying differences in the ways that experts reason, and hence assist with resulting conflict over breast screening. I have used my empirical findings to recommend acknowledgement and respect for the fundamental importance of values in decision making relating to breast screening policies and practices, and to develop methods for how they might be formally incorporated into decision making procedures. Decision makers should be encouraged to receive training in ethics and to adopt dedicated tools, such as the frameworks presented here, to support and guide the incorporation of ethical considerations in deliberations about breast

screening. Reflection and discussion about values will assist decision makers to address values-based conflict and to develop ethically sound breast screening for the future.

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Appendix 1: Normal breast anatomy and physiology

Each breast contains several ductolobular structures that open at the nipple. These structures are composed of branching ducts that decrease in size and terminate in lobules via terminal duct lobular unit. They are somewhat interwoven with each other such that the glandular part of the breast resembles a head of broccoli sitting on the chest with the cut stalk pointing out towards the nipple. The glands are cushioned in fibro-fatty tissue.

The terminal duct lobular unit is the functional part of the breast, proliferating and preparing for milk production in response to hormonal stimulation such as occurs during pregnancy and, to a much lesser extent, during each menstrual cycle. The interglandular stroma, the tissue that lies between the breast glands, is also responsive to hormones. The amount of breast tissue in a given woman is variable, but usually the glands and the interglandular stroma gradually decrease in size once hormonal stimulation ceases (i.e. in the years after menopause) and are replaced by fatty tissue.

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Appendix 2: Breast cancer pathology

Breast cancers are neoplastic growths of cells that have similar characteristics to the cells that line the terminal duct lobular unit. These neoplasms appear to originate in an epithelial cell which accumulates a series of genetic mutations such that cell division becomes increasingly unregulated, with architecturally disorganised growth. If the abnormal cell growth is confined to the duct-lobular system, the cancer is termed carcinoma in situ. Ultimately the abnormal cells invade the basement membrane of the duct-lobular system, and at this stage the tumour is classified as invasive carcinoma. Once cancerous cells have invaded the basement membrane, they can spread into surrounding tissues, including lymphatic and blood vessels. Some cell clusters travel throughout the body in these vessels, seeding distant body sites such as lymph nodes, lung, brain and bones (termed metastases).

This description of neoplastic growth suggests that breast tumours progress through a series of steps, starting out as epithelial cells in the duct system that look slightly abnormal (various types of abnormal, but not obviously cancerous, breast lesions have been described and labelled), eventually become cancerous (“carcinoma in situ”), and ultimately invade into adjacent tissues (“invasive cancer”) where they can potentially metastasise throughout the body. Each stage in this model is identifiable using diagnostic criteria including microscopic, radiologic and clinical appearance. The rate of progression is highly variable and, in many cases, unpredictable.

It is possible that some cases do not conform to this linear progression: for example, some types of abnormal clusters and in situ cancers will only rarely progress to invasion; they are

described by the term “non-obligate precursors to malignancy”. The identification of some of these non-obligate precursors may still be significant however, as they may indicate a general increase in the woman’s likelihood of developing an invasive cancer somewhere else within either breast. Women diagnosed with such lesions may wish to have more frequent screening, or may seek to reduce their breast cancer risk through hormonal treatment or surgical intervention. It may also be that some invasive cancers do not conform to the growth pattern described above; some arise with no identifiable precursor, others never grow, and a few may involute or regress.

This is a simplified discussion of the pathology of breast cancer. I have concentrated on the most common type of breast cancer, and my comments about natural history do not necessarily apply to the rarer sub-types of breast cancer. There is ongoing discussion about how best to usefully categorise different types of epithelial breast changes, particularly the various intraduct changes; I have limited my comments to general observations and ideas about natural history. More detail is available from the texts in the reference list

The natural history of breast cancer has important ramifications for treatment, but also for the usefulness of a program of early detection by screening. For example, if a cancer is destined to grow and invade over a period of years, and if the woman is young enough to be unlikely to die of anything else during that time, early detection by screening will be of benefit, because treatment for localised cancer is likely to be more bearable and successful than treatment for metastatic breast cancer. If, however, the breast cancer was destined to show a different growth pattern, screening may not be of any benefit. That is, screening is unlikely to be helpful for women whose breast lesions are destined to: involute, never change, grow

slowly over tens of decades, or grow rapidly over weeks or months. Screening will also be of limited or no value for woman who are very elderly or otherwise unwell such that they likely to die of other causes. Similarly, screening may or may not be helpful for women who are diagnosed through screening with a type of non-obligate precursor to malignancy, particularly if the implication of the diagnosis is very uncertain, or indicates a real, but small increase in the woman's likelihood of developing cancer, not much beyond what would generally be accepted as the normal (female) level. There is much interest in improving knowledge and understanding about the prognostic significance of these kinds of changes in the breast.

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Appendix 3: Australian breast cancer screening policy and practice

A3.1 Breast screening policy

The publically funded breast screening program in Australia offers biennial screening by mammography to all women over the age of 40 years. This program is particularly targeted towards women between the ages of 50 to 74 years of age. The program is funded and organised through the federal government via its organisation BreastScreen Australia, in conjunction with each of the eight state/territory governments via their organisations: BreastScreen ACT, BreastScreen NSW, BreastScreen SA, BreastScreen WA, BreastScreen NT, BreastScreen Tasmania, BreastScreen Queensland, BreastScreen Victoria.^{1,2}

The program's aims relate directly and indirectly to the improvement of population health. Aims directly linked with population health improvement are: the reduction of breast cancer morbidity and mortality. Aims that are indirectly linked focus on specific service delivery targets, including: maximising early detection of breast cancer in the target population; ensuring screening is provided in dedicated and accredited units that operate with high standards; and ensuring screening access and performance is equitable and acceptable to women across the target population.³ These targets are operationalised through specific performance objectives including, for example, a participation rate of 70% amongst the target age range; identified maximum rates of false positive and false negative results; and the provision of comprehensible and appropriate information to women. A recent formal evaluation of BreastScreen Australia³ by the Australian Government Department of Health and Ageing recommended several changes to the operation of the program, including:

extending the target age range to include women aged 45-49 years and 70-74 years, and removing access for women under 45 years and over 75 years. Some of these have been acted upon, notably an extension of the target age range to 50-74 years. This is in the process of being rolled out across the country and is expected to be completed by 2017.⁴

A3.2 Breast screening practice

The practice of breast screening in Australia is described by focusing in turn on key aspects of the process.

Individual woman: considering mammography screening

A woman becomes aware of the existence of breast cancer screening in a variety of ways. At the age of 50 years, if she is on the electoral roll and her contact details are correct, she will receive a personalised letter in the mail from a local breast screening provider telling her that she should attend screening. This will include a brochure explaining that breast cancer is common and that screening might save her life.⁵ The letter will provide information on how to make an appointment for breast screening. These letters will continue every 2 years until she reaches 69 or 74 years of age, depending on where she lives.⁴

She might also be told that she should attend screening by friends and relatives, by her general practitioner, and by public advertising on the TV, radio, and outdoor advertising (for example at sports fields or bus stops).⁶ Some women will have been already attending screening from the age of 40, particularly if they have a strong family history of breast cancer or if they have a general practitioner who is enthusiastic about screening. If a woman has had

a screening mammogram prior to the age of 50 years, she may already have been receiving recall letters every two years, depending in which state or territory she resides.³

Individual woman: having a screening mammogram

A woman wanting to attend screening may have a choice of where to go, depending on where she lives. Dedicated screening services may be available within public or private hospitals, mobile vans, private centres, shopping centres or department stores such as David Jones. Public services are free; private services may have a charge for the initial mammogram and any follow-up services. When attending her appointment, the woman may be provided with more information about breast screening outcomes, including the possibility of false positive tests and overdiagnosis. The screening test is performed by a radiographer. It includes two mammograms: one with the breast flattened top to bottom (providing the *cranio-caudal* or *cc* view), the other with the breast flattened at an oblique angle from the armpit towards the navel (the *oblique* view). The two-view screening maximises the likelihood that all the breast tissue is visualised in the image. More x-rays may be required if there are any obvious problems with positioning the breast or any technical difficulties. Results will not be available for several weeks.

Mammography reader: interpreting the images

The mammograms may be taken using analogue or, more recently, digital technology. The images will be collated into batches for reading by a radiologist or other trained screening mammogram reader. The reader will spend hours at a time looking at numerous sets of images in a darkened room, spending minutes on each set. If a woman has had

mammograms before, and if they were done at the same clinic, or are otherwise available to the clinic, the reader will compare current mammograms with the previous images. This may help to reassure the reader that any small oddity that has caught their eye has been unchanged for several years, and is therefore not significant.

X-rays pass straight through fatty tissue: that is, fat is radiolucent, and looks black on a mammogram. X-rays get absorbed by, and therefore do not pass through, glandular tissue (which is therefore described as being radio-opaque). These look like white streaks or white shapes on a mammogram, depending on how much glandular tissue is present. Neoplastic glandular cells tend to be tightly clumped together, and show up as densely white, although can be obscured by overlying normal breast glands. Some breast cancers, particularly some types of DCIS, contain calcium, which shows up on a mammogram as a bright white dot, and may sit alongside other calcium dots in a characteristic pattern.

The vast majority of mammograms are normal. If the reader is concerned that a mammogram looks unusual, or is technically inadequate (for example if it does not show all of the breast tissue, or blurred) then they will flag it and the woman will be recalled for repeat mammography. All mammograms are read by two independent readers. If both agree that the mammogram is normal, a letter is issued to the woman, and she is told to return in two years for another screen. If both readers agree that the mammogram is abnormal, she is recalled for further testing. If there is a discrepancy between results, a third reader may review the case, and a final decision will be made about whether or not the woman is recalled.

In a given screening session the radiologist may have to make many decisions about whether or not a mammogram contains abnormal areas. Years of training and experience will enable them to make these decisions. Expertise will be regularly monitored, for example by reviewing the false positive results in a screening unit, to make sure that there are not too many women being recalled and later found to have no abnormalities. If a woman is diagnosed with a cancer on a screening mammogram, or via symptomatic presentation, any previous screening mammograms are reviewed to assess whether or not a radiographic abnormality has been missed (false negative).

Individual woman: Being recalled

A woman who receives a letter recalling her for further testing will be reassured that she is unlikely to be diagnosed with cancer. Normally she will be asked to attend the screening unit at a time when radiologists are present. At this clinic she will have a repeat mammogram, which will be immediately reviewed and compared with the previous images. Often the abnormality is due to an odd shape formed by the overlap of normal glands, which disappears when the glands sit in a slightly different arrangement at this second mammogram. If the abnormality persists then further investigation may be required, and this might include a physical examination, an ultrasound and a biopsy. Depending on the type of biopsy, the woman may have to wait days or weeks for a final result.

Pathologist: interpreting the biopsy

The biopsy may be either a fine needle aspiration (FNA) or a core biopsy. An FNA is taken with a tiny needle, of similar size to those used for blood tests, which removes cells from the area of concern. These can be quickly stained and examined under a microscope; some

clinics might have pathologists available to do this immediately, providing prompt results; other clinics send the specimen to a separate laboratory. Many clinics (and pathologists) prefer a core biopsy, which takes a sliver of intact tissue with a wide bore needle, and needs to be processed for several hours before it can be stained and viewed.

If the pathologist sees neoplastic cells, they begin looking for clues that might indicate what the prognosis of the lesion is likely to be. That is, they are interested in what its natural history might be if left undisturbed and also in how it might respond to the various treatment options that are available. There are many items that are considered, including: whether or not the neoplastic cells are confined to the ducts of the gland or have invaded into the adjacent tissue; the physical appearance of the cells (degree of differentiation in comparison to normal tissue); how the cells are arranged in relationship with each other; and what sorts of receptors are expressed on the surface membrane of the neoplastic cells. Although this is all useful information, it is not conclusive: there is currently no definite way to tell whether or not this neoplasm will continue growing, or if it does, how quickly it might grow, and what the impact of that growth might be.

Individual woman: follow up after biopsy

The woman will return to the clinic for her results. If she is found to have cancer, she may see a surgeon at the clinic, who will discuss some treatment options with her. She may be referred on for treatment at the local hospital, or can ask her general practitioner for a referral to a specific surgeon.

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Appendix 4: Literature search for Chapters 1 and 2

My review topics included: [1] the history of breast screening by mammography, with a particular focus on Australia; and [2] the social and ethical aspects of breast screening by mammography. I wanted to obtain a broad range of perspectives, and thus sought out a mix of sources, including: academic journal articles, scholarly texts, theses, articles and texts from the commercial lay press, and grey literature from government and non-government organisations. The list provided below describes my searching process. My literature searching was systematic and extensive, but not intended to be complete: these were not formal systematic reviews.

1. Electronic database search using the following terms: BREAST and SCREENING; MAMMOGRAPHY and SCREENING; BREAST and CANCER and HISTORY; BREAST and CANCER and SOCIOLOGY.
 - Medline
 - History of science, technology and medicine
 - The philosopher's index
2. Library catalogue search using the following terms: BREAST CANCER; MAMMOGRAPHY; CANCER SCREENING; BREAST SCREENING.
 - National Library Australia
 - University of New South Wales (UNSW) library
 - Sydney University library
 - State Library of New South Wales

3. Hand searching of library shelves adjacent to texts located through library catalogue.
 - UNSW library
 - Sydney University library
4. Catalogue search through large booksellers using the following terms: BREAST SCREENING; BREAST CANCER HISTORY; BREAST CANCER POLITICS; BREAST CANCER SOCIOLOGY; MAMMOGRAPHY.
 - www.amazon.com
 - www.amazon.co.uk
 - www.fishpond.com.au
 - www.bookdepository.co.uk
5. Google Scholar search using the following terms: BREAST SCREENING AUSTRALIA; MAMMOGRAPHY AUSTRALIA (limited to first 200 entries for each term).
6. Index search in the Medical Journal of Australia from 1940-present.
7. Australian national and state breast screening organisations, both government and non government.
 - Cancer Australia, accessed at: www.canceraustralia.gov.au
 - BreastScreen Australia, accessed at:
www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/breast-screening-1
 - BreastScreen NSW, accessed at: www.breastscreen.nsw.gov.au
 - BreastScreen Victoria, accessed at: www.breastscreen.org.au
 - BreastScreen WA, accessed at: www.breastscreen.health.wa.gov.au/
 - BreastScreen Queensland, accessed at: www.health.qld.gov.au/breastscreen/

- BreastScreen Tasmania, accessed at:
http://www.dhhs.tas.gov.au/cancerscreening/information_about_breast_screening
- BreastScreen SA, accessed at:
<http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/healthy+living/recommended+health+checks/breast+screening>
- BreastScreen NT, accessed at:
www.health.nt.gov.au/Womens_Health/Breast_Screen_NT/index.aspx
- BreastScreen ACT, accessed at: www.health.act.gov.au/our-services/women-youth-and-children/breastscreen
- Cancer Council Australia, accessed at: www.cancer.org.au
- Breast Cancer Network Australia, accessed at: www.bcna.org.au
- National Breast Cancer Foundation, accessed at: www.nbcf.org.au
- McGrath Foundation, accessed at: www.mcgrathfoundation.com.au

8. Searching of reference lists in relevant journal articles and books obtained through steps 1-7.

I scanned titles and, if necessary, abstracts or summaries, for likely relevance, rejecting those that did not appear to address my review topics. I concentrated on English language sources that were focused on high-income countries. I assessed the quality of my sources by considering factors such as: type and aim of writing (e.g. opinion piece, empirical research, commercial writing, promotional material); publication process (e.g. presence or not of peer review); quality of empirical research (e.g. transparency of reporting, appropriateness of methods to aims, methodological rigour, whether or not the data justify the conclusions); and

possible conflicts of interest. I relied on good quality sources where relevant (e.g. for information on health outcomes such as cancer incidence, screening rates, mortality figures), and included other sources where appropriate (e.g. to provide information on the range of opinions about breast screening, or methods of breast screening promotion.) My searching was conducted throughout 2012 and 2013, and updated with relevant, high profile sources in 2015.

Appendix 5: Interpreting the evidence on cancer screening

This Appendix contains a published paper that provides further detail on the current controversies associated with interpreting the evidence on cancer screening, including breast screening. A statement outlining contributions to this paper is also provided.

Carter S, Williams J, **Parker L**, Pickles K, Jacklyn G, Rychetnik L, Barratt A. (2015)

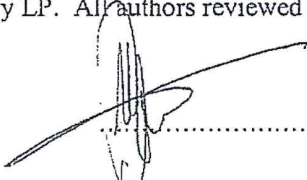
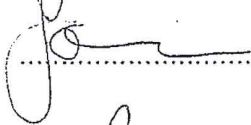
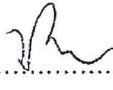
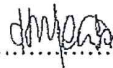
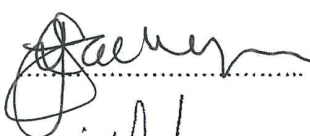
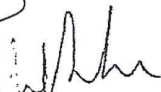

Screening for cervical, prostate, and breast cancer: interpreting the evidence.

American Journal of Preventive Medicine, 49(2):274-285.

Notice of contribution

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The first draft of the section on cervical cancer was written by JW, prostate cancer by KP and breast cancer by LP. All authors reviewed all sections and contributed to subsequent drafts.

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Screening for Cervical, Prostate, and Breast Cancer

Interpreting the Evidence

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Cancer screening is an important component of prevention and early detection in public health and clinical medicine. The evidence for cancer screening, however, is often contentious. A description and explanation of disagreements over the evidence for cervical, breast, and prostate screening may assist physicians, policymakers, and citizens faced with screening decisions and suggest directions for future screening research. There are particular issues to be aware of in the evidence base for each form of screening, which are summarized in this paper. Five tensions explain existing conflicts over the evidence: (1) data from differing contexts may not be comparable; (2) screening technologies affect evidence quality, and thus evidence must evolve with changing technologies; (3) the quality of evidence of benefit varies, and the implications are contested; (4) evidence about harm is relatively new, there are gaps in that evidence, and there is disagreement over what it means; and (5) evidence about outcomes is often poorly communicated. The following principles will assist people to evaluate and use the evidence: (1) attend closely to transferability; (2) consider the influence of technologies on the evidence base; (3) query the design of meta-analyses; (4) ensure harms are defined and measured; and (5) improve risk communication practices. More fundamentally, there is a need to question the purpose of cancer screening and the values that inform that purpose, recognizing that different stakeholders may value different things. If implemented, these strategies will improve the production and interpretation of the methodologically challenging and always-growing evidence for and against cancer screening.

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Introduction

Cancer screening is well established in high-income countries, but its evidence base is constantly evolving and often contentious. This leaves physicians and policymakers in a difficult position, forced to act in the context of methodological complexity and substantive disagreement.^{1,2} Three cases of screening for cancer or cancer risk are considered: cervical, prostate, and breast screening. The unique characteristics of the disease, test, and program in each case are outlined in Table 1. Tables 2–4 catalogue sources of controversy in

each case; these are discussed in more depth below. The concluding section presents five common themes that may help explain the ongoing controversies.

The aim is not to synthesize the evidence but to provide the “backroom” story of the evidence on cancer screening and better illuminate why experts so often disagree.

Cervical Screening

Cervical screening is one of the best-supported and least controversial forms of cancer screening. Nonetheless, there are potentially contentious features of the cervical screening evidence base. These are as follows: (1) dependence on observational data; (2) understanding, communicating, and managing the balance of benefit and harm; and (3) the uncertain future impact of new technologies.

The first challenge in the cervical screening evidence base is the status of the existing evidence. Screening was

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Table 1. Disease, Test, and Program Characteristics in Each Case

	Cervical cancer	Prostate cancer	Breast cancer
Tests used	Pap smear using conventional and/or liquid based cytology ± computer-assisted reading; HPV DNA testing increasing ± cytology; visual inspection with acetic acid/liquid iodine (VIA/VILI) in LMICs	PSA test; new testing methods, including use of biomarkers, are being developed; DRE also used	Mammogram; fixed or mobile mammogram unit; recently widely upgraded to digital technology
When test was invented	Pap test developed late 1930s	First commercial PSA test released in 1986	X-ray used for breast disease 1910s; first screening RCT 1963–1975
When test was first used for screening	Used to screen asymptomatic women from the 1940s	USFDA approved PSA test for prostate cancer screening in 1994	Ad hoc screening from mid-20th century ³ ; population screening programs 1980s onwards (based on publication of results from early RCTs)
What test is designed to detect	Abnormal cells on the cervix (cytology, VIA/VILI) or presence of oncogenic HPV strains (HPV test)	Raised serum PSA levels	Variations in soft tissue radiolucency; originally diagnostic
Relationship between test and target disease	HPV-caused lesions are potential precursors for cervical cancer	Poor; test not developed to screen for cancer; elevated PSA may not indicate cancer risk	Cancers have characteristic (often subtle) soft tissue appearances on x-ray
What results of screening are reported	Lesions: nature and severity (grade) of changes; reporting standards differ; HPV reported by type	PSA levels, expressed as nanograms of PSA per milliliter (ng/mL) of blood	Apparent presence of masses and lesions suspicious for invasive and/or in situ cancer
Contention over test itself	Cytology is prone to human error; terminology and reporting standards vary; sensitivity and specificity estimates vary widely ⁴	There is no meaningful “normal range” for the PSA test in screening	There is variation in what degree of suspicion constitutes a positive screen
Variations between jurisdictions that may change the evidence base regarding benefit and/or harm	IARC recommends 3-yearly cytology screening from 25 years; evidence base pools data from widely varied programs: ⁵ start-age ranges from 18–30 years, interval 1–5 years; reporting standards, terminology and treatment vary	Differences in target age, recommended finishing ages, screening intervals, definition of “abnormal,” biopsy thresholds	Differences in target age, screening intervals, thresholds for recall and biopsy; service studies may differ in participant population age (and therefore underlying cancer risk), follow-up, out-of-study screening
Developments in the test	Tests that detect oncogenic-type HPV may supersede cytology as primary screening test	New test rules in development; variations proposed (free:total PSA ratio, PSA density, velocity, doubling time, prostate health index) for clinical significance; no evidence these improve health outcomes ²	Increasing use of tomosynthesis (integrated 2/3D mammography) and MRI, which may contribute to both benefit and harm

DRE, digital rectal examination; HPV, human papillomavirus; IARC, International Agency for Research on Cancer; LMICs, low- and middle-income countries; MRI, magnetic resonance imaging; PSA, prostate-specific antigen; USFDA, U.S. Food and Drug Administration; VIA, visual inspection of the cervix using acetic acid to highlight precancerous lesions; VILI, visual inspection of the cervix using Lugol's iodine to highlight precancerous lesions.

established in parts of Europe and North America between the late 1940s and early 1960s, and data from those programs, rather than from controlled trials, provide the evidence base for cervical screening effectiveness. Observational studies compared screened and unscreened populations and showed reduced cervical cancer incidence and mortality in the former.^{5,30,31} This evidence base clearly shows that cervical screening

reduces morbidity and mortality: what is less clear is who to screen, when, and how to optimize benefit and minimize harm.

The cervical screening evidence base is susceptible to the well-known biases of any observational study.¹ It is not clear how these biases should be taken into account. In addition, the observational data about cervical screening cross jurisdictions in which there are substantially different programs

Table 2. Main Issues in Cervical Cancer Screening

Issue	Explanation
Incidence and mortality of cervical cancer is low in high-income countries	The incidence of cervical cancer is much lower than, e.g., breast or prostate cancer, so number needed to screen over many years to avoid one death is high. ⁶
Cervical screening reduces morbidity and mortality from cervical cancer	Early Nordic observational studies suggest a mortality benefit from screening using the Pap test. Organized programs confer greater benefit than opportunistic screening. ⁵
There is no RCT evidence from high-income countries	Because Pap test screening for cervical cancer was introduced so early, it was not possible or ethical to conduct an RCT of its effectiveness.
RCTs are being conducted in LMICs	These will be a useful evidence base for LMICs.
It is easy to overstate the benefits of cervical cancer screening because the underlying mortality rate is low	Because incidence is low, number needed to screen is high and absolute risk reduction low. Statements of benefit may obscure the relatively small absolute number of people affected. E.g., mortality is often said to have halved in the decade following commencement of organized screening in Australia: this is accurate, but the absolute change was from only 4/100,000 to 2/100,000 women.
Most cervical lesions regress	It has been recognized since the 1970s that most cervical lesions will not progress to cervical cancer.
It is not clear what proportion of lesions regress, or which lesions will regress	It may never become clear which lesions will regress or what proportion of them will regress. CIN3 progression to cancer has been estimated at 12%, ⁷ 20%, ⁶ and 30% ⁸ in different studies.
Overtreatment is difficult to measure and to manage	The majority of treatment is overtreatment, but as it is not possible to identify which lesions will regress, this may not be resolvable with the technology currently available. There are vastly more abnormal results than there are invasive cancers, especially in women aged <25 years; e.g., in Australia in 2010 the incidence of invasive cancer in women aged <25 years was 1.5/100,000, but 40,000 of the 250,000 screens in women aged <25 years returned an abnormal result. ⁹ Perinatal morbidity in treated women is the main iatrogenic harm of concern. ¹⁰
The evidence base is affected by differences in program design between countries	Evidence about cervical screening comes mostly from monitoring data from screening programs. However, different countries run their programs differently. They use different tests, screening ages, and screening intervals. They classify and report on their programs using different terminology and standards. Then the data from these very different contexts are combined. This has implications for the evidence base.
Screening technology is changing	Because of HPV vaccination, a move away from cytology seems likely; an alternative future might be mass HPV screening with cytological examination of those with positive HPV tests. It is unclear what the incremental benefits and costs of these new technologies over existing screening programs will be. This is a rapidly evolving part of the evidence base in cervical screening.

CIN3, Cervical intra-epithelial neoplasia; HPV, human papilloma virus; LMICs, low- and middle-income countries.

and reporting standards. This means that these observational data from different settings may not be as easily comparable as is often assumed (Table 1). To minimize bias, meta-analysis of RCT evidence is the preferred method for estimating benefit and harm in screening. RCT evidence of different screening technologies, and combinations of technologies, is emerging. This may add more certainty to

the cervical screening evidence base, although some of the findings from RCTs in low- and middle-income countries (LMICs) may not be transferable to other settings.³²⁻³⁵

The second challenge in this evidence base concerns understanding, communicating, and managing the balance of benefit and harm; this problem has several dimensions. It is easy to inadvertently overstate the

Table 3. Main Issues in Prostate Cancer Screening

Issue	Explanation
Most prostate cancer is not life threatening	Although prostate cancer can be life threatening, the vast majority of cases are indolent.
Early trials of PSA screening were of poor quality	Early trials—which reported very positive findings—had serious methodological problems, including low participation in screening, failure to randomize, and failure to analyze by intention to screen.
Large RCTs are currently underway	The ERSPC trial ¹¹ and the USA PLCO ¹² trial have made interim reports but are ongoing. These are the only large, methodologically sound trials of PSA screening conducted to date.
There is controversy over the design of the current large RCTs	ERSPC included different countries using different screening tests and procedures. Those screened in the trial were more likely to be treated in a University hospital. The Swedish subset of ERSPC compared volunteer screenees (probably a healthier group) to whole-population controls (particularly significant because Sweden was one of only two, out of seven, subgroups to report statistically significant reductions in prostate cancer mortality after 11 years). These patterns are likely to bias results in favor of screening. In PLCO, > 50% of controls were screened during the trial, and 44% of participants had previously been screened. Methodologists disagree on whether these biases are fatal to the results of the trials.
PSA screening may decrease prostate cancer death	Some trials suggest reductions in incidence of prostate cancer death. Observational studies in highly screened populations suggest lower prostate cancer mortality.
PSA screening is unlikely to decrease all-cause mortality	Only ERSPC has reported a mortality benefit, which was very small in absolute terms. 1,055 men would have to be screened to prevent one death from prostate cancer over 11 years. ¹³
The PSA test is not prostate cancer-specific	PSA test has poor sensitivity and specificity for detecting prostate cancer. A PSA > 4.0 ng/mL produces a 6.2% false positive rate but detects only 20.5% of cancer cases. ¹⁴ PSA test cannot distinguish increased cancer risk from other common conditions, e.g., benign prostatic hyperplasia, prostatitis. Certain medications (e.g., finasteride), ejaculation, and prostate manipulation can also increase PSA levels.
PSA test manufacturers and PSA thresholds vary between studies, laboratories, and clinicians	Studies and laboratories employ more than one kind of PSA test and different abnormal thresholds. The evidence base is thus hard to interpret because of lack of comparability. Conventional threshold for further investigation is 4 ng/mL, but men with PSA levels 4–10 ng/mL may not have prostate cancer, ¹⁵ and men with results < 4 ng/mL can show histological evidence of prostate cancer. ^{16,17} Lowering the threshold below 4 ng/mL would increase overdiagnosis and overtreatment of clinically unimportant disease. ^{18,19} A meaningful threshold for screening may not exist because of the test's poor sensitivity and specificity; i.e., the PSA test has little utility as a screening tool for prostate cancer. There is currently no alternative test available.
PSA screening can increase the likelihood of receiving treatment	In the U.S., e.g., up to 90% of men with prostate cancer diagnosed as a result of PSA testing receive treatment. ²⁰
Prostate cancer treatment can produce considerable negative consequences	Treatment can result in erectile dysfunction or impotence, anxiety, urinary incontinence, bowel dysfunction, or death.

ERSPC, European Randomized Study of Screening for Prostate Cancer; PLCO, Prostate Lung Colorectal and Ovarian Cancer trial; PSA, prostate-specific antigen.

mortality benefit of cervical screening, particularly in high-income countries. This is because mortality from cervical cancer in high-income countries is considerably lower than for cancers such as breast and prostate. This was true even prior to widespread Pap testing. For

example, the age-standardized mortality rate from cervical cancer in the United Kingdom was approximately 8/100,000 in 1971, compared to 37.5/100,000 for breast cancer and 20/100,000 for prostate cancer.³⁶ Thus, even substantial proportional (or relative risk) reductions in

Table 4. Main Issues in Breast Cancer Screening

Issue	Explanation
Mortality benefit exists	Most studies show mortality benefit from organized mammographic screening—especially for women aged 50–70 years—of approximately 20%. ^{21–24}
The extent of mortality benefit is contentious	Estimates of benefit vary considerably. Different study types are used, including RCTs, observational studies, and modelling. Meta-analysis of RCTs is widely regarded as the best way to identify population benefits, but different meta-analyses include or exclude different RCTs because of differing judgments about study quality. ^{21–24}
Mortality benefit is less than originally thought	Recent meta-analyses of RCTs suggest that benefit is lower than suggested by the earliest studies. This can be partly attributed to problems in quality with some of the RCTs. It has been hypothesized that treatment improvements in recent decades may leave less room for screening to have an effect and make older trial data less relevant. ^{21–24}
The harm from false positive screening tests varies between programs and populations	The rate of false positives varies as a result of factors such as the following: <ul style="list-style-type: none"> ● Test factors, e.g., equipment quality; skill of the clinicians reading the mammograms ● Differing policies and standards regarding acceptable levels of false positives and false negatives ● Frequency of screening in the program (increased frequency tends to increase the absolute number of false positives) ● Individual participant factors (e.g., greater breast density in some women, including pre-menopausal women and women taking hormone replacement therapy [HRT]) that can make mammogram interpretation more challenging (and false positives more common) ● Population factors: the frequency of false positives in part depends on the positive predictive value of the test, which depends on the prevalence of disease in the screened population. This depends on population risk profile (e.g., younger women have lower incidence).²⁵
The extent of overdiagnosis is contentious	Estimates of overdiagnosis vary as a result of factors including the population studied; research questions asked (e.g., total cancer or invasive cancer only); methods used (e.g., comparing incidence in intervention and control arms of RCTs, comparing observational annual incidence data, comparing observational cumulative incidence data, using simulated population models); correction for possible biases such as lead time; and fundamental assumptions when estimating overdiagnosis in models. ^{1,10,26,27}
Biological consequences of in situ disease is unclear	Before the onset of screening, in situ disease was mostly diagnosed in conjunction with an invasive cancer. It was not anticipated to be a common isolated finding on screening. It is unclear what the right response to increased diagnosis of in situ disease should be. Knowledge of the natural history of in situ breast diseases is improving but still incomplete. Diagnosis and management are controversial, especially for less aggressive diseases (e.g., low-grade DCIS), where risk of death is only slightly increased but surgery to negate the risk may be extensive. ^{21–24}
There are small radiation harms of screening	Harm from radiation during mammography is generally agreed to be real and may be greater in women screened more often (e.g., those identified as carrying potentially harmful mutations in the <i>BRCA1</i> or <i>BRCA2</i> genes). ^{28,29} However, in screening of the general population, these risks are extremely small and likely to be further reduced by the implementation of digital mammography.

BRCA1/BRCA2, Breast Cancer susceptibility gene 1 and 2; DCIS, ductal carcinoma in situ.

mortality attributed to screening may represent only small reductions in the absolute number of deaths prevented in well-resourced countries (Table 2). Cervical cancer, however, remains a significant burden and leading cause of cancer mortality in some low-income regions.³⁷

In addition, the treatments triggered by screening may be unnecessary and harmful in some cases. Cervical screening reduces cancer incidence as well as mortality. This is because it detects cellular abnormalities on the cervix, or pre-cancerous lesions, caused by human papillomavirus (HPV) (Table 1). Cervical cancer is a

rare outcome of persistent infection over a long time. However, cellular abnormalities are common: there is an estimated lifetime incidence of 40% in women born since 1960.⁶ Also, progression appears to be less linear than originally thought,³⁸ and most HPV infections regress spontaneously. This means that four of five women with dysplasia may be treated unnecessarily,⁶ but at present it is not possible to identify which individual high-grade lesions will regress, and can be left untreated, or will progress, and require treatment (Table 2).

The evidence does suggest a solution, however: to focus on minimizing harm, particularly in women aged <25 years. The evidence shows that (1) HPV infection is most likely to spontaneously regress in this group; (2) paradoxically, these women also experience more abnormal cytology, treatment, and cervical incompetence and perinatal morbidity as a result of treatment; and (3) crucially, there is no mortality benefit in screening this age group.^{10,39} As a result, many countries are delaying commencement of screening until age 25 years (Table 1), recommending screening thereafter only every 3–5 years, or both.^{40,41} Although this change is supported by the evidence, in many jurisdictions women continue to be screened earlier and more often than these guidelines would support.^{5,42,43}

Finally, it is important to anticipate the future impact of new technologies on the evidence base and on practice.^{44,45} Research increasingly supports screening women aged ≥30 years using an oncogenic-type HPV test instead of or in addition to cytology.³² The U.S. Preventive Services Taskforce (USPSTF), for example, now recommends that women aged 30–65 years can screen with a combination of cytology and HPV testing every 5 years if they wish, rather than with cytology alone every 3 years.³³ The U.S. Food and Drug Administration (FDA) has recently approved the use of HPV testing alone as a primary screening test,⁴⁶ which seems likely to result in further revision of recommendations. The recommendations are somewhat ahead of the evidence—with the exception of an Indian cluster RCT,³⁴ primary HPV testing has not yet shown mortality benefit. Similarly, comparative benefits and harms of different sequential combinations of HPV and cytology testing are not yet clear. However, RCTs of newer screening technologies (e.g., HPV tests, including self-testing and testing in vaccinated populations, and computer-assisted cytology reading) are underway. HPV vaccination will further reduce underlying risk in the population and thereby potentially reduce the relevance of the existing evidence on cervical screening.

Screening for Prostate Cancer

Unlike cervical screening, prostate-specific antigen (PSA) testing for prostate cancer risk is intensely contested⁴⁷;

this includes contention over the relationship between evidence and practice. Important issues include (1) inconsistency between the findings of different trials (and tension over the interpretation of observational findings); (2) variation in tests and thresholds for abnormality within and between studies; and (3) evidence suggesting that the PSA test performs poorly for screening purposes.

The first challenge is the quality and interpretation of research about the efficacy and effectiveness of PSA testing. Observational data from highly-screened communities are sometimes used to argue that testing reduces prostate cancer mortality.^{16,48,49} However, as noted earlier, findings from observational studies may be misleading because of characteristic biases such as lead time, length time, and selection bias.^{2,18} Early RCTs were of poor quality (Table 3).^{2,18} Since then, two ongoing RCTs have reported results: the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the U.S. Prostate, Lung, Colorectal, and Ovarian Cancer (PLCO) Screening Trial. PLCO has shown no effect on prostate cancer-specific or all-cause mortality.⁵⁰ ERSPC reported reduced prostate cancer mortality in screened men but no change in all-cause mortality.¹¹ There is considerable controversy over trial design (Table 3). Although difficult to quantify, frequency of testing and follow-up and type of treatment provided after diagnosis are likely to affect outcomes reported from trials.^{12,13,51}

Expert bodies increasingly advise against PSA screening. The USPSTF concluded that the mortality benefit is very small and outweighed by risk of harm.⁵² The American College of Preventive Medicine has similarly concluded that populations should not be routinely screened with the PSA test, owing to insufficient evidence.⁵³ The Australian National Health and Medical Research Council evidence guideline on PSA testing in asymptomatic men has recently concluded that there is no effect of PSA testing on all-cause mortality and that no conclusions can be drawn about prostate cancer mortality.⁵⁴ These decisions are consistent with the evidence, which suggests that PSA testing may reduce the short-term risk of dying from prostate cancer by a very small amount, at the cost of a much greater risk of harm, including from false positive results, overdiagnosis, and overtreatment. The question this raises is: If a screened man will not die any later than an unscreened man, is it meaningful to prevent him from dying of prostate cancer in particular? And at what cost (harms to the man as well as expense to the man and the health system) should this goal be pursued? This question seems to divide experts, not least according to whether they care for men with the disease or have experienced it themselves.

The second problem in the PSA testing evidence is interpretability and comparability of PSA results. This is an issue for many screening tests (Table 1), but especially for the PSA test. Manufacturers and laboratories employ divergent PSA calibrations, producing different readings from the same sample.⁵⁵ Even when identical methods are used, thresholds set to separate “normal” from “high-risk” PSA levels often differ. Within and between studies, different standards are often combined, potentially invalidating conclusions.^{16,56} Tests and thresholds used by different countries participating in large trials often vary (Table 3), and trial study groups have been unable to identify acceptable PSA cut offs for prostate cancer screening. This makes it difficult to compare study results and apply them to real-life settings.

The final problem with interpreting the evidence about PSA testing is addressing the potential for harm. The evidence suggests that sensitivity and specificity of the test are poor (Tables 1 and 3), which means cancers are missed (poor sensitivity) and false positives are common (poor specificity). The evidence suggests that PSA testing increases diagnosis of indolent disease, frequently cascades to diagnostic biopsies and follow-up treatments, and produces physical and psychological harms and costs: for every life saved by the PSA test, up to 48 men may be overtreated (Table 3).⁵⁷ Determining whether this is acceptable requires difficult debate over the nature of a good outcome, and what harm or expense that outcome might justify.

Screening for Breast Cancer

Like the evidence for PSA testing, the evidence for breast screening has been controversial. Important features of this evidence base include (1) uncertainty regarding the extent of breast cancer mortality reduction benefit; (2) uncertainty regarding the extent of harm; and (3) disagreement about managing in situ disease.

The first challenge for the evidence on breast screening is that despite a considerable body of research, the degree to which breast screening reduces breast cancer mortality remains unclear. The evidence base includes 11 RCTs (1971–2006), numerous observational studies, and mathematical models. It is probable that an invitational program of breast screening by mammography offers a population breast cancer mortality benefit, particularly for women aged 50–70 years. If poorer-quality RCTs are removed from meta-analyses, this benefit is reduced, but by how much is unclear (Table 4). Absolute and relative benefits are lower in women aged <50 years.⁵⁸ Also, treatment has greatly improved in recent decades, so including RCTs from the 1970s–1990s may overstate the benefit of screening

(Table 4).^{1,21–24,26} The degree to which widely observed declines in breast cancer mortality are attributable to improvements in treatment remains contested.⁵⁹ It is unclear how this can be resolved. Incremental changes in technology—from film mammography to digital mammography, tomosynthesis (integrated two-/three-dimensional [2/3D] mammography) and magnetic resonance imaging (MRI) to screen high-risk women—may also affect the balance of screening benefits and harms.^{60,61}

The second concern is the extent of harm that is caused. Invitational mammography programs cause harm, including false positives and overdiagnosis. The absolute rate of false positives can vary according to the equipment used, skill and experience of film readers, test thresholds, and screening frequency (Table 4).²⁵ Although the rate of false positives per screen may be low, they accumulate; thus the chance of false positive recall or biopsy over a lifetime is much higher. Increasingly, evidence suggests that breast screening produces overdiagnosis of both invasive and in situ breast cancer. Although experts agree that mammography screening causes overdiagnosis, there is disagreement on its extent. A recent meta-analysis suggests that, in women invited to screening, there is an 11% lifetime risk of overdiagnosis as a proportion of cancers that are diagnosed, and a 19% risk during the active screening period.^{21,24} Harms, especially overdiagnosis, may tend to outweigh benefits in women aged >70 years as they age.⁶² However, the relevant evidence is highly contentious for methodological and other reasons explained in Table 4.^{26,27}

The final challenge in this evidence base concerns ductal carcinoma in situ (DCIS), which represents approximately 17%–34% of screen-detected cases and 20%–25% of all newly diagnosed cases of breast cancer in the U.S.⁶³ Women are rarely diagnosed with DCIS because they experience symptoms: DCIS is diagnosed almost entirely as a result of screening. Overdiagnosis of DCIS is widely considered an important harm of mammographic screening. However, the evidence is not clear on either the natural history of DCIS or how aggressively DCIS should be treated. More research is needed to evaluate treatments for in situ disease.^{21,26}

What Characteristics of the Screening Evidence Base Could Explain Expert Disagreement?

In high-income countries, cancer screening is a familiar feature of preventive medical care. Screening is expected—with good reason—to be informed by evidence. Across these

three cases, there are two less-often discussed tensions and three more explicit tensions that help to explain why interpreting the evidence is such a difficult task.

Tensions in the Evidence Base That Are Discussed Less Often

Two tensions in the evidence base are under-examined: the comparability of data between studies and contexts, and the impact of technological developments. These tensions are also difficult to resolve and potentially destabilizing.

Data from different contexts may not be comparable, particularly for observational data from monitoring studies. As shown, the evidence base contains data from different times, countries, and programs, and from populations with varying event rates (Table 1). Transferability of this evidence is difficult for several reasons. Because screening trials are particularly large and need long follow-up to show effects, they can be especially susceptible to the passage of time. When early trials were conducted, screening techniques were less developed, treatments less effective, cancer incidence lower, and cancer mortality often higher. Breast screening evidence, for example, includes decades-old trials; treatment has progressed substantially since they were conducted. Evidence from screening trials is also susceptible to local variation (e.g., in disease biology, event rates, and age distribution), not least because screening is applied to whole populations, not just people who are ill. As HPV vaccination is implemented differently around the world, for example, the underlying event rate for cervical cancer will change dramatically. The resource intensiveness of cancer screening trials also means that (1) few trials are done (leaving less evidence to interpret); (2) trials are often funded by industry (changing the research questions); and (3) trials are somewhat dependent on local screening and treatment practices (e.g., target age, screening intervals, testing techniques, follow-up time, available treatment). The variability and transferability of screening evidence is a challenge for methodologists, and even more so for clinicians and policymakers, as the characteristics on which the evidence depends are not always made clear in reporting.

The second under-examined tension is that screening technologies affect evidence quality; thus, evidence must evolve with changing technologies. Cancer screening relies on complex cascades of technology for collecting, imaging, analyzing, and interpreting possible changes in human bodies. Without the technology, there is no screening, but as technology evolves, it potentially makes existing evidence obsolete.⁶⁴

The evidence on PSA is hampered by poor technology. The PSA test has limited sensitivity and specificity,

studies and laboratories use multiple test types and different thresholds, there is no meaningful “normal range,” and new test rules do not appear to change patient outcomes. Some propose using test results only within, rather than between, patients, but the poor test characteristics of PSA make even this problematic. It is understandable that clinicians want to retain some tool to measure prostate cancer risk.⁶⁵ However, given the test characteristics of the PSA, it may not be possible to generate a meaningful evidence base about its use in populations.

The cervical screening evidence base is shifting because of changing technology; tests that detect oncogenic-type HPV may become the primary form of screening in vaccinated populations. Mammography remained relatively constant in the 20th century, changing only incrementally from film to digital mammography. In the 21st century, we face substantial technological change, with moves to tomosynthesis (integrated 2/3D mammography) and MRI screening of high-risk women. Although tomosynthesis is receiving considerable attention in the lay press and peer-reviewed literature, attempts to estimate its effects have been based on opaque assumptions and limited evidence. It seems possible that both MRI and tomosynthesis will enhance both the benefits and harms of screening, but at present this is unknown.^{60,61}

Acknowledged Tensions in the Evidence Base

Three other, more explicit, tensions are over the quality of evidence of benefit, the relatively new evidence regarding screening harm, and risk communication.

The quality of the evidence of benefit from screening varies, and the implications of this evidence are contested. When one expert says to another, “You are wrong about the evidence on screening,” she is likely to mean this: “I disagree with the criteria that you have used to separate good-quality studies, which should be included, from poor-quality studies, which should be excluded. I therefore disagree with your conclusion.”

The cancer screening evidence base contains observational studies, RCTs, and modeling of widely varying quality and with disparate results. Early studies of screening generally suggested greater benefit, and later studies less benefit, which may be because early trials were poorly designed (e.g., PSA) or because recent treatment improvements leave less room for screening to provide benefit (e.g., breast screening). Even new trials contain methodological flaws (e.g., PLCO, ERSPC), and methodologists often disagree about study design, particularly over whether screened and unscreened groups are comparable.

New RCTs are expensive and logistically challenging, and so are rare. Thus, new conclusions generally arise from re-analyses of existing research findings rather than from new trials. Researchers performing meta-analyses must decide on criteria for including and excluding studies. The recent Marmot review of the evidence on breast screening demonstrates that this is possible,²¹ even in high-profile situations, but disagreement over criteria is likely to remain. And when new analyses produce new findings, those whose settled beliefs are challenged may perceive the chosen criteria as arbitrary or incorrect. This highlights the importance of transparency regarding how and why meta-analyses are conducted.

The second acknowledged tension is that evidence about harm is relatively new, and there are gaps in that evidence and disagreement about what it means. Initially, cancer screening researchers focused on measuring screening benefits; they have only recently turned to potential harm. For all three cases—cervical, prostate, and breast cancer (including DCIS)—there is limited evidence about which instances of disease or pre-disease are aggressive and require treatment, and which will be indolent or regress. Because of this, many people will be overtreated and may be harmed. Researchers are trying to address this gap by studying the mortality benefit of treatment for small, Grade 1, node-negative breast cancers, for example, or the genetic profile of aggressive versus indolent prostate cancers. This work may assist in the future. In the meantime, existing knowledge suggests opportunities to reduce harm. For example, there is currently no way to determine which cervical lesions will regress or progress. However, epidemiological data demonstrate that women aged 18–25 years are most likely to have unnecessary treatment, experience harm from treatment, and fail to benefit from treatment. This has led some jurisdictions to restrict cervical screening to women aged >25 years.

Even when evidence about screening harm emerges, experts often disagree about what it means and how to respond. This may be in part because public health and medical professionals have learned to think in a particular way, and have taught citizens to think similarly, of cancer and pre-cancer as progressive and life-threatening, and screening as one of few defenses against this threat. For the first several decades of screening research, harm was rarely measured. Although later research suggested that screening may harm, it may be difficult for this evidence to reach public attention given the powerful cultural meaning of cancer death.^{66,67} New facts about screening harm are hotly contested, with regard both to their accuracy and their implications. And screening programs continue to be

evaluated primarily against increasing participation targets, rather on the likely balance achieved between benefit and harm.

For example, it is generally accepted that prostate biopsies and prostate cancer treatments are likely to produce harm. This is taken as a fact, but that fact is interpreted very differently. Some argue that most screen-detected prostate cancers are indolent, so most diagnosis is overdiagnosis, and most harm done is unnecessary. They conclude that insurers or policy-makers should constrain clinicians who test healthy men, thus preventing harm. Others take a different view, that without PSA testing, clinicians have no way of diagnosing tumors that would develop or metastasize. These experts tend to take the view that insurers or policymakers should leave testing open to clinicians and allow the possibility of harm to be dealt with via more judicious decisions about treatment. Their opponents might counter with studies showing that men diagnosed with prostate cancer generally proceed to treatment rather than “watching and waiting.”²⁰ Although each party can present data of some kind to support their claims, it is worth remembering that data become evidence only through interpretation and that experts are susceptible to biases in this interpretive process.^{68,69}

The final acknowledged tension is that evidence about outcomes is often poorly communicated, despite the evidence about communication. Researchers and programs tend to express outcomes using relative risks, which incorporate baseline risk and are easier to generalize across contexts. However, research shows that relative risks encourage lay people and clinicians to overemphasize benefits and minimize harms. This has been acknowledged as ethically problematic, potentially biasing or manipulating people’s perceptions, misleading them, and undermining their autonomy.⁷⁰ If experts are obliged to communicate honestly with citizens—an obligation that seems supportable—this becomes an urgent issue to address for all forms of cancer screening.

Conclusions

The benefits and harms of screening are often finely balanced—more than anticipated when screening was established. There are both unique and shared characteristics of cervical, prostate, and breast screening that help to explain the challenge of balancing benefit and harm. These include the incomparability of data from different times, places, and programs; the instability of the very technology on which screening is based; disagreement on which studies are sufficiently well designed to be taken seriously; gaps in knowledge; and disagreement about

how to understand newly emerging evidence of harm. This suggests five principles for evaluating and using the evidence:

1. attend closely to transferability;
2. consider the influence of technologies on the evidence base;
3. query the design of meta-analyses;
4. ensure harms are defined and measured; and
5. improve risk communication practices.

However, even more fundamental are questions about the purpose of screening and who should make decisions about screening. Should insurers or policymakers leave screening options open for clinicians and patients to choose? Or should they be directive, promoting some forms of screening and limiting others to minimize harm? Should community engagement and deliberation guide screening policy and practice? And what should the purpose of screening be? There are many potential aims of cancer screening, including preventing cancer death, reducing all-cause mortality, minimizing anxiety, maximizing cost efficiency, and minimizing avoidable harm. These different aims reflect different values, which may differ between patients, clinicians, funders, and policymakers. Questions about the evidence base need resolution. This should be complemented with clear thinking about the aims of screening. Only when the aims of screening are clear will researchers be able to generate an evidence base sufficient to assist decision making, and clinicians be able to best support their patients to make good screening decisions.

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Appendix 6: Literature search for Chapter 3

Search string

An example of the search string for literature review of empirical studies on what influences people's views about breast screening by mammography.

Medline via OvidSP, August 2015

1. breast [30115]
2. mammography [29766]
3. 1 or 2 [55364]
4. mass screening [86238]
5. 3 and 4 [7130]
6. attitude [166454]
7. perception [22747]
8. 6 or 7 [186346]
9. 5 and 8 [586]
10. limit 9 to (English language and year="1990-Current") [555]

Inclusion criteria

- Empirical research article published in a peer-reviewed journal
- Research performed on a developed country

- Research performed on a country with established (organised or opportunistic) mammography screening procedures
- Research on cancer screening more generally *if and only if* breast screening is specifically addressed

Exclusion criteria

- Research focused only on women at high risk of breast cancer
- Research focused only on second or subsequent breast screening visits

Appendix 7: Full data list (published papers) for Chapter 3

1. Absetz P, Aro AR, Sutton SR. Experience with breast cancer, pre-screening perceived susceptibility and the psychological impact of screening. *Psycho-oncology*. 2003;12(4):305-18.
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Appendix 8: Data analysis for Chapter 3

Table A8.1. Data analysis for Chapter 3 (worked examples)

Study	Country	Sample	Study design	Aim of study
Achat et al., 2005	Australia	Women	Quantitative	Increase screening attendance
Bortoff et al., 1998	Canada	South Asian women	Qualitative	Increase screening attendance
Ahmad et al., 2001	Canada	Primary care practitioners	Quantitative	Increase screening attendance
Alcaez et al., 2002	Spain	Women	Quantitative	Increase screening attendance
Avis-Williams et al., 2009	USA	Underserved women	Qualitative	Increase screening attendance
Banks et al., 1995	USA	Women	Quantitative	Increase screening attendance
Black et al., 1995	USA	Women under 50 years	Quantitative	Increase informed decision making
Bryant et al., 1992	Canada	Rural and disadvantaged women	Quantitative	Increase screening attendance

Appendix 9: Ethics committee documents for empirical study (Chapters 4 to 8)

This Appendix contains the documents confirming ethics committee approval for my research including approvals for various amendments to my participant recruitment and materials. The initial letter of approval, dated 7 August 2012, contains an error in the AUD RED Reference for the Cancer Institute of New South Wales Population & Health Services Research Ethics Committee. It reads HREC/12/CIPHS/399 but should read HREC/12/CIPHS/46 (my italics). The correct reference is provided in subsequent letters from the Cancer Institute of New South Wales.

Dr Stacy Carter
Centre for Values, Ethics & the Law
The University of Sydney
Level 1, Medical Foundation Bldg (K25)
92-94 Parramatta Road
Camperdown NSW 2006

7 August 2012

Dear Dr Carter,

NSW Population & Health Services Research Ethics Committee

AU RED Reference: HREC/12/CIPHS/399

Cancer Institute NSW reference number: 2012/06/399

Project Title: Evaluating cancer screening: context, evidence, values and ethics

Thank you for your correspondence dated 16 July 2012 responding to a request for further information/clarification of the above referenced study, submitted to the NSW Population & Health Services Research Ethics Committee (Executive) for single ethical and scientific review. The Committee reviewed your response at its meeting held on 1 August 2012 and I am pleased to inform you that full ethical approval has been granted.

The Committee approved the following documents:

- Researcher response letter, dated 16 July 2012
- NSW National Ethics Application Form, v2, submission code AU/1/9D2D06, dated 2 May 2012
- Protocol, Version 1, dated 2 May 2012
- Information for Participants – Units, Version 2, dated 11 July 2012
- Information for Participants – Workshop, Version 2, dated 11 July 2012
- Participant Consent Form – Units, Version 2, dated 11 July 2012
- Participant Consent Form – Workshop, Version 2, dated 11 July 2012
- Survey Tool, Version 1, dated 2 May 2012
- CV of Stacy M. Carter, PhD
- APP1023197 GRP Assessment Summary
- NSW Privacy Form

The NSW Population & Health Services Research Ethics Committee (Executive) has been accredited by the NSW Department of Health to provide single ethical and scientific review of research proposals conducted within the NSW public health system.

The Committee is a joint initiative of the Cancer Institute NSW and NSW Department of Health. The Committee has been constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* and relevant legislation and guidelines.

Please note that ethical approval is valid for **5 years**, conditional on the following:

- Principal investigators will immediately report anything which might warrant a review of ethical approval of the research, including unforeseen events that might affect continued ethical acceptability.
- Proposed amendments to the research proposal or conduct of the research which may affect the ethical acceptability of the research are to be provided to the NSW Population & Health Services Research Ethics Committee for review.
- The NSW Population & Health Services Research Ethics Committee will be notified giving reasons, if the research is discontinued before the expected date of completion.
- The Principal Investigator will provide an annual progress report to the NSW Population & Health Services Research Ethics Committee and at the completion of the study.

You are reminded that this letter constitutes '*ethical approval*' only. This research project must not commence at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. It is your responsibility to forward a copy of this letter together with any approved documents as enumerated above, to all site investigators for submission to the site's Research Governance Officer. Where relevant, copies will also need to be provided to the CHeReL and the data custodian.

For further information about the NSW Population & Health Services Research Ethics Committee, please refer to our website www.cancerinstitute.org.au/research.

Should you have any queries about the ethical review of your research proposal, please contact Kate Lowrie, Admin Support Officer – Ethics on 02 8374 5616 or email ethics@cancerinstitute.org.au.

The NSW Population & Health Services Research Ethics Committee wishes you well in your research endeavours.

Yours sincerely,



Sharon Falleiro
Ethics Coordinator
Cancer Institute NSW
Population & Health Services Research Ethics Committee

Ref: [SA/KFG]

7 September 2012

Dr Stacy Carter
Centre for Values, Ethics & Law in Medicine (VELIM)
The University of Sydney
Email: stacy.carter@sydney.edu.au

Dear Dr Carter

Title: Evaluating cancer screening: context, evidence, values and ethics [Ref. 15245]

PhD Students: Jane Williams, Kristen Pickles, Gemma Jacklyn & Lisa Parker

The Executive of the Human Research Ethics Committee (HREC) has reviewed your study to include the above PhD students. The Committee acknowledges your right to proceed under the authority of the *NSW Population & Health Services Research Ethics Committee*.

The Human Research Ethics Committee advises that you consult with The University of Sydney **Audit and Risk Management Office** (http://sydney.edu.au/audit_risk/) to ensure that University of Sydney staff/students and premises are adequately covered for the purpose of conducting this research project.

Any modifications to the study must be approved by the *NSW Population & Health Services Research Ethics Committee*. A copy of any approved modification, approved progress report and any new approved documents must be provided to The University of Sydney HREC for our records.

Please do not hesitate to contact Research Integrity (Human Ethics) should you require further information or clarification.

Yours sincerely



Dr Stephen Assinder
Chair
Human Research Ethics Committee

cc: jane.h.williams@sydney.edu.au
gemma.jacklyn@sydney.edu.au
lisa.parker@sydney.edu.au
kristen.pickles@sydney.edu.au

Dr Stacy Carter
Centre for Values, Ethics and the Law in Medicine
School of Public Health
Room 162
K25
University of Sydney
NSW 2006

07 May 2013

Dear Dr Carter,

NSW Population & Health Services Research Ethics Committee

AU RED Reference: HREC/12/CIPHS/46

Cancer Institute NSW reference number: 2012/06/399

Study Title: Evaluating cancer screening: context, evidence, values and ethics

Thank you for your correspondence of 1 May 2013 responding to a request for further information from the NSW Population & Health Services Research Ethics Committee.

I am pleased to advise that the following documents have been approved:

- CI NSW Request for Amendment form, dated 4 March 2013
- Breast screening recruitment email, Version 2, dated March 2013
- Focus Group recruitment, Version 1 dated March 2013
- Participant Information Sheet (Breast Screening), Version 4, dated April 2013
- Participant Information Sheet Prostate screening, Version 4, dated April 2013
- Participant Information Sheet Cervical Screening Interviews, Version 4, dated April 2013
- Participant Information Sheet Cervical Screening Focus Groups, Version 4, dated April 2013
- Prostate screening recruitment wording, Version 3, dated April 2013
- Protocol for verbal consent, Version 1, dated March 2013

The NSW Population & Health Services Research Ethics Committee has been accredited by the NSW Ministry of Health to provide single ethical and scientific review of research proposals conducted within the NSW public health system.

The Committee is a joint initiative of the Cancer Institute NSW and NSW Ministry of Health. The Committee has been constituted and operates in accordance with the National Health

and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* and relevant legislation and guidelines.

For further information about the NSW Population & Health Services Research Ethics Committee, please refer to our website www.cancerinstitute.org.au/research.

Should you have any queries about the ethical review of your research proposal, please contact me on 02 8374 3562 or email ethics@cancerinstitute.org.au.

Yours sincerely,



Virginia Turner
Ethics Coordinator
Cancer Institute NSW

Dr Stacy Carter
Centre for Values, Ethics and the Law in Medicine
School of Public Health
Room 162
K25
University of Sydney
NSW 2006

13 September 2013

Dear Dr Carter,

NSW Population & Health Services Research Ethics Committee

AU RED Reference: HREC/12/CIPHS/46

Cancer Institute NSW reference number: 2012/06/399

Study Title: Evaluating cancer screening: context, evidence, values and ethics

Thank you for your recent correspondence notifying of changes to the above referenced study, submitted for single ethical review to the NSW Population & Health Services Research Ethics Committee (Executive). The Committee reviewed your amendments at its meeting held on 3 September 2013, and I am pleased to advise that ongoing ethical approval has been granted.

The Committee approved the following documentation:

- Cover Letter, dated 26 August 2013
- CI NSW Request for Amendment form, dated 26 August 2013
 - Request to add to the existing recruitment protocols and wording.
- Breast Screen Participant Information Sheet Interviews, Version 5, dated August 2013
- Breast Screening Recruitment email, Version3, dated August 2013
- Additions to general recruitment protocol.

The NSW Population & Health Services Research Ethics Committee has been accredited by the NSW Ministry of Health to provide single ethical and scientific review of research proposals conducted within the NSW public health system.

The Committee is a joint initiative of the Cancer Institute NSW and NSW Department of Health. The Committee has been constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* and relevant legislation and guidelines.

You are reminded that this letter constitutes *'ethical approval'* only. This research project must not commence at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. It is your responsibility to forward a copy of this letter together with any approved documents as enumerated above, to all site investigators for submission to the site's Research Governance Officer. Where relevant, copies will also need to be provided to the CHeReL and the data custodian.

For further information about the NSW Population & Health Services Research Ethics Committee, please refer to our website www.cancerinstitute.org.au/research.

Should you have any queries about the ethical review of your research proposal, please contact me on 02 8374 5615 or email ethics@cancerinstitute.org.au.

The NSW Population & Health Services Research Ethics Committee wishes you well in your research endeavours.

Yours sincerely,



Samantha Dawes
Administration Support Officer
Cancer Institute NSW

Appendix 10: Recruitment for empirical study (Chapters 4 to 8)

This Appendix contains a version of the recruitment email and participant information sheet (see **Chapter 4**).

Recruitment email

Re: Mammographic screening study

Dear xxx

I am writing to request an interview with you as part of a large NHMRC-funded research project about cancer screening policy and practice in Australia. I am undertaking the breast cancer screening case study within this project. I aim to explore the evolution of mammographic breast cancer screening in Australia, with particular attention to scientific, social and ethical factors, and to look closely at how we might best make decisions about the future of breast cancer screening. To do this I plan to speak with a wide range of people who work or research in the field, and I am seeking your participation in this capacity. *I am particularly interested in your opinion because ...*

If you choose to be involved I would like to conduct an hour-long interview with you. Your contribution will remain completely confidential. I will not disclose who participated in the study, and will completely de-identify the data so that no participants can be recognised.

A detailed Participant Information Statement is attached to this email. The Chief Investigators for the project are Stacy Carter, Lucie Rychetnik, Alexandra Barratt and Ian Kerridge. The Associate Investigators are Vikki Entwistle, Les Irwig, Ian Olver, Sally Redman and Glenn Salkeld.

I know that you are very busy but I would be most grateful if you could manage to spare an hour of your time and share your knowledge with me. I look forward to hearing from you.

Kind Regards,

Lisa Parker
MBBS (Hons), MBioethics
PhD Candidate | Centre for Values, Ethics and the Law in Medicine (VELiM)
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***** **Attach the participant information sheet** *****

UNDERSTANDING DEVELOPMENTS AND DEBATES WITHIN MAMMOGRAPHY SCREENING IN AUSTRALIA

INFORMATION FOR PARTICIPANTS - INTERVIEWS

Introduction

You are invited to participate in an important research project about breast cancer screening. This study is part of a larger project examining cancer screening policy and practice within Australia.

You are invited to participate in the breast cancer screening arm of the study. As you know, opinions about breast cancer screening vary. For example, people disagree about whether some women receive unnecessary treatment as a result of screening, and if they do, how we should respond. **In this project we aim to understand such disagreements and what should be done about them.** We are using well-established qualitative methods to gather the widest possible range of views about breast cancer screening. **We do not have preconceived notions about what is right and wrong: instead we are trying to understand why people and organisations take contrasting positions, and what we might do to resolve differences.** We are analysing data from in-depth interviews and focus groups with consumer advocates, clinicians, epidemiologists, people involved in screening service provision, and other stakeholder groups.

The purpose of this project is to answer the following research questions:

- What are the range of factors that influence thinking on breast screening policy and practice?
- What contributes to the controversies around mammographic breast cancer screening?
- What common ground exists between breast screening stakeholders?
- How might we best make decisions about future directions within breast screening?

This project is administered through the University of Sydney. The investigators are:

Name	Main area of expertise	Affiliation
Stacy Carter (Chief Investigator (CI))	Public health ethics and qualitative health research	Centre for Values, Ethics and the Law in Medicine and Sydney School of Public Health, The University of Sydney
Lucie Rychetnik (CI)	Evidence in public health and qualitative health research	Sydney School of Public Health and Centre for Values, Ethics and the Law in Medicine, The University of Sydney
Alexandra Barratt (CI)	Screening epidemiology	Sydney School of Public Health, The University of Sydney
Ian Kerridge (CI)	Bioethics	Centre for Values, Ethics and the Law in Medicine, The University of Sydney
Vikki Entwistle (Associate Investigator (AI))	Ethical and social research	University of Aberdeen
Les Irwig (AI)	Epidemiology	Sydney School of Public Health, The University of Sydney



Lisa Olver (AI)	Oncology, bioethics	Cancer Council Australia, The University of Sydney
Sally Redman (AI)	Knowledge translation in health	SAX Institute
Glenn Salkeld (AI)	Health economics	Sydney School of Public Health, The University of Sydney

The field work on this study will be done by Lisa Parker, a PhD student from the University of Sydney.

This project is funded entirely by the National Health and Medical Research Council (**APP1023197**).

Interviews

You are invited to participate in an interview. This will be an opportunity to talk about your own experience and how you think about cancer screening policy and/or practice. We will canvass your general opinions on breast screening as well as specific stories from your experience within the field of breast screening.. Some of the questions that we will be asking you include what you think of the current screening program, what you think would be an ideal breast cancer screening program, and how you think breast screening will change in future. Interviews will last around 60 minutes depending on how much you want to say. If you agree, the interview will be digitally recorded.

Feedback

If you wish, we can provide you with a transcript of your interview. When analysis of the interview data is complete, we will provide you with a summary of the findings. This will occur approximately in the second half of 2014.

Data retention

In all studies coordinated through the Centre for Values, Ethics and the Law in Medicine, we give participants the option to consent to having their information retained in a de-identified form for further research and teaching. Alternatively you can opt to have the data destroyed 7 years after the project ceases. This will be entirely up to you.

Risks

This is a low-risk project. The most significant risk is unwanted identification in reporting. To minimise this risk, we will substitute a code for your name in all transcripts as soon as they are prepared, and we will remove any details that might reveal your identity. Code sheets will be kept in a locked filing cabinet. Digital audio files will be kept on password protected servers at all times.

Benefits

This research study is designed to further knowledge about the range of views on cancer screening and to support decisions about cancer screening in the future. It may not be of direct or immediate benefit to you, but will provide you with opportunities to contribute your thoughts and experiences. For the study to be useful, it is critical that we gather the widest possible range of views on breast cancer screening. We hope very much that you will take part as it will strengthen the quality of our final analysis.

Voluntary Participation

Participation in this study is entirely voluntary. You do not have to take part. If you do take part, you can withdraw at any time without having to give a reason. There will be no consequence to you if you do not wish to take part, or wish to withdraw.

Withdrawal from the study can be organised by contacting Lisa Parker on 0406 758998 or the lead Chief Investigator Stacy Carter on 02 9036 3407, whichever you would prefer.

Confidentiality



THE UNIVERSITY OF
SYDNEY

All the information collected from you for the study will be treated confidentially. The interview will be digitally recorded. The digital audio file will only be accessible to the chief investigators, project coordinator and participating PhD students. It will be kept on a password protected server. Field notes and interview transcripts will be available only to the Chief Investigator team, project coordinator and participating PhD students who will meet weekly to analyse the data.

The Associate Investigator (AI) team will meet with the Chief Investigator team twice a year to discuss the analysis. The AI team will not have access to the raw transcripts or field notes. The study results will be presented at conference and in scientific publications, including the workshops planned for the end of the project. However your contribution will remain completely confidential. We will not disclose who participated in the study, and will completely de-identify any observations and quotations used so that no participants can be recognised.

Further Information

If you would like any further information please do not hesitate to discuss this with Lisa Parker who will answer any questions you may have. If you would like to know more at any stage, please feel free to contact Lisa Parker (0406 758998) or Dr Stacy Carter (02 9036 3407), the lead Chief Investigator for the project, at any time.

This information sheet is for you to keep.

Ethics Approval and Complaints

This study has been approved the Cancer Institute NSW Population & Health Services Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Ethics Coordinator who is the person nominated to receive complaints from research participants. You should contact them on 02 8374 5600 and quote HREC/12/CIPHS/46.

Appendix 11: Interviews for empirical study (Chapters 4 to 8)

This Appendix contains information about how I conducted interviews for my empirical study.

A11.1 Introductory discussion with participants

Interviewer: Thank you for agreeing to participate in this study. I came to be interested in this area when I was working as a breast physician in the UK, and I noticed that some of my colleagues were really enthusiastic about the screening program, and others were less so. And there has been quite a bit written in the literature and also in the media about breast screening, and what the program should look like. Plenty of people are happy with things the way they are, but others are not. Given that we all have access to the same evidence, this made me wonder what was behind these differences, what else people are thinking about, what else is important to people. So I'm interested in exploring that range of opinion, particularly amongst people who work in the field, either in clinical practice or research, or policy or people who play an important public role in promotion or fundraising for breast cancer screening and listening to the kinds of things that contribute to those different opinions. So this study is an effort to try and explore the issue of screening in more detail and enlisting the help of people such as yourself to try and explain and understand what is behind different views.

A11.2 Obtaining consent

Consent for interview

Give participant the consent form to read through, or read out to participant over the phone.

Consent for recording

Ask participant if they consent to this interview on breast cancer screening being recorded and used to inform the project that I have previously outlined with them.

(See consent form overleaf)



**EVALUATING CANCER SCREENING:
 CONTEXT, EVIDENCE, VALUES AND ETHICS**

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 AUSTRALIA
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PARTICIPANT CONSENT FORM

I, _____
 [name]
 Of _____
 [address]

have read and understood the Information for Participants on the above named research study and have discussed the study with _____.

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I freely choose to participate in the following elements of this study and understand that I can withdraw at any time. I also understand that the research study is strictly confidential.
 [please respond to all questions]

I agree to be included in unidentified field notes made about the daily work of my organisation related to cancer screening policy or practice NO YES

I agree to participate in an interview (*I understand that the interview will be digitally audiotaped, and I agree to this*). NO YES

Would you like your data retained in an un-identified form for further research and teaching, or destroyed 7 years after the project ceases? Destroyed Retained

I hereby agree to participate in this research study as detailed above.

NAME: _____.

SIGNATURE: _____.

DATE: _____.

NAME OF WITNESS: _____.

SIGNATURE OF WITNESS: _____.

A11.3 Interview questions

Do not need to follow precisely; tailor questions to participant's responses and to their areas of expertise.

1. Can you tell me the **story of your involvement in breast cancer screening**, starting from when you first got involved and taking us up to the present?
2. And now: describe **what you do in a typical working week**, and maybe touch on the scope of any other professional activities that involve breast screening such as committee meetings and so on.
 - Including, but not restricted to work that involves breast screening – just to give me a clearer idea of the scope of your involvement in the program
3. **Think back to the late 1980s – early 1990s** when breast cancer screening was being introduced in Australia. Did you have any particular views on it then? How have they changed?
4. **Views on the current Australian breast cancer screening program?**
 - I know you have written about breast cancer screening in ... Can you expand on that?

(If interviewees seem to be repeating the 'party' line of the institution that they work for, you could remind them that the interview is confidential and say, 'you don't have to answer this question, but I wonder how your personal views compare with the institutional policies and practices, and whether there might be any points of difference?')
5. **Would you like to see any changes to the current program?**

- What would your ideal program be?
 - Reasons for why the current program is different from your ideal? e.g. logistical/financial issues, or deeper differences about the place of screening?
 - Feed in what others have suggested and ask for comments; e.g.
 - Begin at 45 or 40 and continue indefinitely
 - 3 yearly screening
 - Decrease funding for screening, spend on treatment including better access
 - More information
6. **What would it take to make such changes happen?**
- What might be the barriers to change?
 - What process would you like to see Australia follow? Feed in what others said:
 - Methodologists only
 - Independent people
 - Community involvement
7. There are **many different ideas**, about breast cancer screening. Can you comment on these?
- There are some who hold very **extreme views** about breast cancer screening. How do you respond to these ideas?
 - What do you think drives those views? If ignorance –would they have a different point of view if they were more informed?
 - If you could talk to – the public / Gotzsche etc, what would you say?
 - Can you see any good in their position? Is there anything about what you think such people are trying to achieve that might lead to some common ground with yourself?

8. *(If the topic hasn't yet surfaced)* Ask specifically about **overdiagnosis**
 - Evidence suggests some cancers found at screening would never have come to clinical attention in that person's lifetime.
 - What are your thoughts on this? What level of overdiagnosis do you work with - e.g. is it: non-existent; exists but not a problem; a problem
 - How much responsibility should screening programs take for reducing overdiagnosis; how much should we tailor the program to minimize overdiagnosis?
9. *(If the topic hasn't yet surfaced)* as about **communicating with women**.
 - You may know that some places are looking at re-doing the breast screening leaflet. What are your thoughts on what should be said to women?
10. **Future** Obviously you can't read the future, but given your expertise and experience, what do you think will happen? (NB: I am trying to write about what *should* happen, so it is useful to start with what *could* happen).

(Version: June 2013)

Appendix 12: Data analysis for empirical study (Chapters 4 to 8)

This Appendix contains personal notes that I wrote and used to guide my data analysis, along with examples and excerpts from the various tools that I used to assist with organising and synthesising my data.

A12.1 Coding index

Use the following table to code interview transcripts.

(see table overleaf)

Table A12.1. Index for coding interview transcripts

List of topics and concepts	Shorthand used for coding transcripts
Chronology	
Of breast cancer	<i>bc hx</i>
Chronology of screening including influences on screening program in Australia	<i>screening hx</i>
Current Australian program	<i>screening now</i>
Future in breast cancer including screening	<i>future</i>
Views on screening	
Overall thoughts on breast cancer screening	<i>on bcs</i>
What is important about bcs	<i>what is important</i>
How own views are formed	<i>how decides</i>
Harms, including how to balance harms and benefits	<i>b&h</i>
Changes would like to see / ideal program	<i>changes</i>
Justification for suggesting those changes or having stated views	<i>reasons</i>
Why own view is right	<i>why right</i>
Evidence & more	
What evidence is accepted or used as right (numbers, names)	<i>evidence</i>
Why that evidence is used e.g. what are the influences on self regarding interpretation of evidence	<i>infl on ev (overlap with how decides – see above)</i>
General ideas about evidence	<i>about evidence</i>
Views of other people	
Comments on different / contradictory evidence	<i>diff ev</i>
Comments on possible influences on other people / why they think the way they do	<i>influences on others</i>
Engaging with others	
What would there have to be in place to have a dialogue with others, especially those who hold contradictory views	<i>moving forward</i>
Views on how to ‘move forward’, how future policy decisions should be made	<i>process</i>
Other	
Way of talking about women as participants / patients	<i>talks about women</i>
Personal breast screening or breast cancer story e.g. self, family, friend	<i>personal</i>

(Version: May 2013)

A12.2 Memo 1

Notes on writing Memo 1

After each interview, immediately write a short memo addressing the following points:

- Biographical data
- What sort of person is s/he?
- Immediate response / impression about the interview
- What did I learn?
- How was this interview similar/different to others?
- What are the main points (what must I *not* forget)?
- How does the interview help me answer my research questions?

Include the memo with the transcript.

Memo 1 example

Memo 1

(Date and identifying information removed)

Prompt interview – just the following week after email. Happy to talk. Embarked immediately on a discussion about overdiagnosis, and was surprised later in the interview when I suggested that others had told me that breast screening was not controversial in general medical and public circles.

Essential points: [1] overdiagnosis nowhere near as big an issue in breast screening as in prostate screening [2] benefits of breast screening probably bigger than suggested, because

most studies include data from the very beginning of screening, when in fact there were mistakes / incomplete roll out – studies of benefit should only look at the program when in steady state / fully functioning / problems ironed out, e.g. 10 yrs into it [3] ecological studies are problematic, because too many assumptions; most people who are concerned about a high level of overdiagnosis rely on ecological studies.

Suggested – for breast cancer it's a judgement call, about balancing benefits and harms (unless, as in the case with prostate cancer, the harms are really very significant). Doesn't think the public should be asked to make judgements about treatment – people like ... are paid to give advice and so that's what they should do. People might think they feel strongly about valuing something (e.g. not losing their hair) – but in fact, when in a certain situation and faced with limited options, that might turn out not to be so important after all, so even asking the public to make decisions based on what they value can be problematic.

A12.3 Memo 2

Notes and template for Memo 2

After reading and coding the transcript, write Memo 2: i.e. summarise the participant's views using the following template. Include relevant quotes from the transcript. Include line references for summarised views and for quotes.

- Chronology of breast cancer
- History of breast cancer screening in Australia
- Current breast cancer screening in Australia
- Overall view of breast cancer screening

- Suggested changes
- Reasons for change
- Views on harms
- How own views are formed – evidence used
- How own views are formed – other
- What is important about evidence?
- What is important overall?
- Other people's views – evidence; other
- Future - best process for moving forward?

(Version: September 2013)

Memo 2 example

Memo 2

Italics indicate direct quotations from interview transcript. (Numbers in brackets indicate line reference from transcript).

Chronology of breast cancer

Currently – a very breast aware society, therefore few women are presenting late – this was occurring even before screening started because of: 1. Early presentation and 2. Modern treatment, prognosis for breast cancer is good even without screening (721).

Hx of bcs in Australia

Current bcs in Australia

Overall view of bcs

Crude approach (394)

This is an issue that is obviously very active on the international stage (975).

Suggested changes

Stop inviting (754) - women assume invitation = encouragement (880) = means *Someone somewhere has weighed up the pros and cons and decided ... on balance – that screening is a good thing (343; 355); if you stop inviting then many women will stop coming (which will be appropriate) I think if women weren't invited, I really think that would have a big impact on what women actually do ... I think if that letter never arrived, there'd be a lot of people who – who it would just not – it wouldn't happen (943; 954).*

Continue to allow screening, and give women info that it is an option (756; 912; 878) *I wouldn't like to ban it in the sense that I think those [very high risk] women should have the option, but I do not think we should be encouraging women at average risk to be screened the way they currently are.*

At least – invitation should not come from service provider because they are judged on their success in terms of participation rates and thus cannot be expected to provide appropriately balanced info about pros and cons (344; 355) invitation from a separate body (e.g. Cancer Australia) and with lots of thought about type and format of info re: pros and cons (764; 773).

Remove the KPI (Key Performance Indicators) for BreastScreen to identify a certain % of small cancers – because that changes the spectrum of disease that we are diagnosing and increases overdiagnosis (797; 842).

Don't include women over 70 - retrograde step (964) because that increases overdiagnosis (because of co-morbidities) *I just think it's terrible to think that women aged in their seventies will be having, you know, surgery with or without radiotherapy and going on to five to 10 years of endocrine therapy for a condition which they would otherwise have never known they had (813).*

Screening should be individualised (392; 880); only screen those at high risk (e.g. very strong family history or BRCA or past history of chest irradiation (333) not those at average risk – because currently we cannot say that the benefits of screening definitely outweigh the harms (418) this is because: 1. Treatment so much better 2. Overdiagnosis is a big harm.

Reasons for change

Views on harms

How own views are formed – evidence used

the figures cannot lie (randomised trial data) (267); *clear evidence* of overdiagnosis from the RCT data (640); overdiagnosis ?10% (269).

RCT evidence – 20% mortality reduction – but these are pre-treatment revolution and so not likely to be true (609; 617) the estimate of benefit from the trials no longer really applies. (623).

Marmot: *very conservative estimate was that for every life saved, there would be at least three cases of overdiagnosis (674).*

A12.4 Chart

Transfer a summarised version of Memo 2 into the Chart.

(See table overleaf)

Table A12.2. Excerpt from the Chart

Participant details	#23, male, researcher, (location removed to preserve anonymity)	#25, female, consumer advocate, (location removed to preserve anonymity)
Hx of br ca		
Hx of bcs in Aust	data suggested benefit; debate about parameters; seemingly good value (little data); feasible program, well scrutinised; political driver; previously: screening committee made decisions, abolished by Howard; 70% particip aim is “made up”; 2 yearly screening - easier to remember	
Bcs in Aust today	no defined process of decision making; widely seen as sacrosanct; assumption about high particip rate is a myth	advocacy groups get contacted by media after new evidence released; advocacy groups involved in advisory working parties; in Vic - no screening within BS after bc dx; in WA can get screening in BS still; 50% funding from c’wealth & state; funding on 3 yearly basis; frustration about set up – c’wealth & state input - hard to make changes
Overall view of bcs	prob beneficial; an empire in own right, much like other health interventions; living - should respond to changes	good; early detection leads to less radical treatment; contributes to dec mortality
Suggested changes		consistency across states e.g. about access after bc dx
Reasons		
Views on harms		overdx - about DCIS; problem is about whether to treat or watch; need more research & info to women about this; no real concept of this as a 'harm' - only harm from participation in bcs is 10 min of your life
How views are formed: evidence		hard to understand; 40% of Aus bc are picked up through bcs
How views are formed: other		meets a lot of women who were pleased to be dx through bcs; bc is common; belief in the value of screening
What is important (evidence)		

Table continues overleaf

Participant details	#23, male, researcher, (location removed to preserve anonymity)	#25, female, consumer advocate, (location removed to preserve anonymity)
What is important (overall)	accountability for public health program (evaluate benefit & safety); autonomy - information & views of public; cost; having a framework to decide about public health interventions; having experts justify their values	having people attend screening; informing women about risks of treatment vs watching; reducing the impact of bc on Aus community; having info about bcs available for those who want it; economic considerations; public debate (tho not at expense of deterring screening)
How other's views are formed: evidence		same data - diff interpretation, hard to know why; looking for evidence to back up theory rather than just looking at data
How other's views are formed: other	politics; economics (oft used to support pre-existing convictions); values	
Infl on women		
How to proceed	committee with defined TOR relevant to public health (i.e. values); advisory committee to review evidence	consensus amongst clinicians before public debate; research into how to target screening and direct treatment
Who to have		
Prediction		

A12.5 Rolling Memo

Reflect on the recent interview and on previous interviews, and add relevant information into Rolling Memo.

Rolling memo excerpt

[Numbers in square brackets indicate aliases for interviews]

How own views are formed – what evidence is used

Many experts named individuals or particular trials as being influential, esp their own; others talked about types of evidence.

- XX was initially very influential [1,3,4].

- Own evidence used [2,3,4,5,6,13,14,17,20,24].
- International evidence is good [17]. Important to use objective / impartial evidence (Marmot paper) [5,6,25] .
- Canadian trials seem well conducted [11].
- YY ‘writes well’ [9].
- Research from Cas Dickson: 50% benefit from those who get screened is good study [17].
- Marmot paper – 20% benefit are pre-treatment figures so unlikely to be correct; although RCTs are gold standard, they are out of date [24,25]; estimate of overdx ‘conservative’ [14]; incredible that he didn’t use observational data – what does that say about those studies that were all approved by ethics committees [16]; wouldn’t rely on someone who has no experience in the area [17]; relies on the Marmot paper [26] because independent [21,25]; Marmot’s view of overdx was that it can’t be determined at an individual level – until we can do that, we can’t call it a harm [30].
- Trials, level 1 evidence [18,21].
- Evidence as converted into guidelines [18].
- Only use (the 5) RCTs without Clinical Breast Examination in the intervention arm [20].
- Modelling studies that explain 50% mortality reduction due to treatment [13].
- Important to use service studies, RCTs are hypothesis generating, but not proving of effectiveness in the real world [4,24].
- Due to lack of alternatives (insufficient good quality local recent evidence) we are forced to rely on outdated RCTs and less than ideal observational studies, which

entail us to make assumptions that are easily challenged by those who don't like the conclusions [16].

- Population studies can tell us that incidence of later stage cancer has not decreased as expected if the increase in diagnosis of small (early) cancers is effective (i.e. probably most of the small cancer diagnoses are overdiagnosis) [20].
- Focus groups about how to give info [21].

Most experts thought evidence was a major influence on their views, though some thought it was uncertain or difficult to interpret:

- Evidence is crucial e.g. for ensuring program quality [24].
- Lots of evidence compared to other health interventions [25], though still evidence is not clear cut [25].
- Evidence underpins everything; keeps up with new literature; but evidence is uncertain and open to different interpretations [26].
- Evidence is crucial [28] but statistics very hard to understand [28].
- Doesn't understand the evidence, i.e. unable to personally evaluate the evidence base [31].
- Evidence controversy very confusing for a self confessed 'failed' epidemiologist [9] or anyone because of so many possible biases [24].
- All the published literature seems credible; impossible to know what to believe so no specific figures used, just general concepts – including acceptance that over-detection occurs [10].

Others talked more explicitly about evidence being important but unavailable:

- Main issue is lack of evidence of benefit [11], still in stage of evaluating, no clear conclusions yet [29].
- Aware of uncertainty around evidence of benefit [6] or harms [24]; evidence not clear cut [25].
- The literature has shown mortality benefit so we have to believe it; but not completely convincing as concurrent treatment improvement – would like more proof [23].

Different ideas about the evidence and what it shows:

- Clearly proven that screening saves lives [27]; clear that screening enables early diagnosis and early diagnosis works [29].
- Long studies of low grade DCIS show that 60% progress @ 30 years [7,13].
- The increased proportion of small/early stage cancer diagnoses together with reduced population breast cancer mortality is evidence of success [7].
- Low participation rates explain limited population mortality benefit [8].
- Doesn't believe stated evidence relating to likely individual benefit [8].
- No evidence of benefit for <50 ; marginal evidence of benefit for >50 [11].

? Maybe different interpretations of evidence is partly because people use different types of evidence: [4] thinks that breast cancer screening produces a dramatic benefit, of the scale rarely seen in public health research (because [4] looking at relative figures?); [6] thinks that the benefit is modest, measured in days rather than in years as seen with smoking cessation (because [6] is looking at absolute figures?).

Some people talk about evidence in relation to harms:

- Evidence about benefit – but not population evidence about so-called ‘harms’ because the interpretation of outcomes being a harm is a personal, value judgement (and not something that the epidemiology people should take on) [12].
- Should look for evidence about harms as well as benefits [24].
- Hard to know how much incidence is due to overdiagnosis and how much due to lifestyle changes, but we do know that there have been lifestyle changes and these must have had an effect [17].

How own views are formed – other

Professional experience – clinical:

- Clinical bias to avoid death [1], ‘life before limb’ attitude [18]; exposure to patients - focus on individuals [5,13].
- Observation bias - seeing women with small screen detected cancers who are able to be cured [21,23], though recognises anecdotes cannot be used to set up population screening [21]; seeing older women present symptomatically after exiting screening program [22]; seeing small tumours with metastases, large tumours that do well, [22]; we have all seen seemingly low risk cases with metastases/multifocal lesions [19,23]; seeing low grade lesions that recur as nasty cancers [23]; regular clinical exposure to patients in whom screening has not benefited [8], anecdotes, clinical experience [25].
- Clinical knowledge of what breast cancer patients were like pre screening era [1,13] or in countries without education and screening [17].
- Pathologists can’t find all positive margins – better to treat [13].

Professional experience – research:

- Public health bias - population focus and responsibility [4].
- Epidemiology training on how to think quantitatively [6] rather than qualitatively.
- Epidemiology background – influences ideas on importance of research, need to basing public health decisions on evidence, the way we look at & weigh evidence [16].

Professional experience – other:

- Meeting a lot of women who were pleased to have their cancer diagnosed early through BreastScreen (advocacy group person) [31].

Intuition/common sense:

- Partly based on knowledge of changes since RCTs, e.g. life expectancy,[23,24] changes in treatment, changes in imaging [8].
- Nothing magic about 50 year olds re: incidence, risk [11].
- Should try to minimise use of intuition and judgement [16].
- Breast screening picks up 40% of the breast cancer in Australia, so it must be a good tool [31].
- Breast cancer is common and kills thousands of women every year so screening is important [31].

Appendix 13: Returning results to participants

This Appendix contains information about how I returned results to the participants of my empirical study.

Individual email to participants

Dear xxx

Re: mammographic screening study

In 2013 you were kind enough to participate in a project as part of my doctoral studies, and gave me an hour of your time for an interview regarding your ideas and views on breast screening in Australia. Together with my supervisors, we have spent the last year analysing the data from 33 interviews that I undertook, and have submitted our findings in several papers to peer-reviewed journals. The first of these papers has now been published, and since many participants expressed an interest in hearing about the outcome of the project, I have great pleasure in providing the link for the following publication:

Parker L, Rychetnik L, Carter S. Values in breast cancer screening: an empirical study with Australian experts. *BMJ Open* 2015;**5**:e006333

<http://bmjopen.bmj.com/cgi/content/full/bmjopen-2014-006333?ijkey=4fede9Ou6qJV7y&keytype=ref>

We hope to have our other papers published over the course of this year, and will forward these to you when they become available. If you do not wish to receive any more emails from me about this, please let me know.

I would like to thank you again for your generosity in participating in this study. We very much hope that our findings will be useful resources for those who continue to be involved in breast screening policy and practice in the future.

Kind Regards,

Lisa Parker

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