

# VIEWS & REVIEWS

## NO HOLDS BARRED

# A trial to extend breast cancer screening may be unethical

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A trial extending the ages at which UK women are eligible for breast cancer screening was registered in 2010. Its target is “at least” three million participants, with follow-up until “at least the late 2020s.”<sup>1</sup> But was government policy to extend it, regardless of the trial’s findings?

Currently, only women aged 50-70 are routinely eligible for breast screening. This trial randomises centres to invite women for extra screening at ages 47-50 and 70-73, or not.

On 9 July 2014 David Walker, chairman of the UK National Screening Committee—which makes evidence based recommendations to the government—told the Commons science and technology committee, “We have not decided to implement the age extension, although we support the trial to see whether we should be implementing it. Once the trial is complete we will make a recommendation, but that will be some time in the future.”<sup>2</sup>

Public Health England says that age extension is being phased in and is expected to be complete in England by 2016.<sup>3</sup> But what if the trial shows that it is ineffective?

The research ethics committee application for the trial, whose chief investigator, Julietta Patnick, is director of NHS Cancer Screening Programmes, noted “limited evidence” on the value of extra screening, adding, “Regardless of this study, the age range for breast screening in the NHS Breast Screening Programme is being extended from ages 50-70 to ages 47-73.”

Department of Health policy in 2007<sup>4</sup> and 2011<sup>5</sup> was for screening services to extend the age range or take part in the trial<sup>5</sup>—but this wasn’t merely politics.<sup>4</sup> Mike Richards, the department’s national clinical director for cancer and end of life care, told *The BMJ* in 2011, “A further extension from 47-73 is, on the advice of independent academics and with the support of the ACBCS [Advisory Committee on Breast Cancer Screening], being introduced through randomisation.”<sup>6</sup> The policy to extend the ages of breast screening seems to have been used to justify the trial in the research ethics committee application; but the benefits of age extension are uncertain.

And do women even know that they are participants? The researchers request no individual consent. The usual screening invitation comes with extra information saying that “the

phasing-in of the age extension is randomised” so that “the net benefit can be scientifically evaluated.” But it does not mention the possibility of net harm.

In the ethics committee application, the risk of overdiagnosis to three million more screened women is not spelled out. It justifies potential harms because the age range “is being extended anyway.”

And yet, the National Screening Committee has given no recommendation for age extension. What’s more, Michael Marmot’s 2012 review stated, “The impact of breast screening outside the ages of 50-69 years is very uncertain.”<sup>7</sup> Shouldn’t someone tell this to the women taking part in the trial?

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: I’m an NHS GP partner, with income partly dependent on Quality and Outcomes Framework points. I’m a part time undergraduate tutor at the University of Glasgow. I’ve written a book and earned from broadcast and written freelance journalism. I’m an unpaid patron of Healthwatch. I make a monthly donation to Keep Our NHS Public. I’m a member of Medact. I’m occasionally paid for time, travel, and accommodation to give talks or have locum fees paid to allow me to give talks but never for any drug or public relations company. I was elected to the national council of the Royal College of General Practitioners in 2013.

Provenance and peer review: Commissioned; not externally peer reviewed.

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- 1 ISRCTN Register. Evaluating the age extension of the NHS Breast Screening Programme—trial registration. 2010. [www.controlled-trials.com/ISRCTN33292440](http://www.controlled-trials.com/ISRCTN33292440).
- 2 Science and Technology Committee. Oral evidence: national health screening, HC 244. 9 July 2014. <http://bit.ly/1stEWIJ>.
- 3 Public Health England, NHS Breast Cancer Screening Programme. What does the NHS Breast Screening Programme do? [www.cancerscreening.nhs.uk/breastscreen/screening-programme.html](http://www.cancerscreening.nhs.uk/breastscreen/screening-programme.html).
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- 5 Department of Health. Improving outcomes: a strategy for cancer. January 2011. [www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/213785/dh\\_123394.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213785/dh_123394.pdf).
- 6 Richards M. An independent review is under way. *BMJ* 2011;343:d6843.
- 7 Marmot MG, Altman DG, Cameron DA, Dewar JA, Thompson SG, Wilcox M; Independent UK Panel on Breast Cancer Screening. The benefits and harms of breast cancer screening: an independent review. October 2012. *Br J Cancer* 2013;108:2205-40. <http://www.nature.com/bjc/journal/v108/n11/full/bjc2013177a.html>.

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