

Critics say wider breast screening trial 'unethical'

- 11:50 10 November 2014 by [Clare Wilson](#)
- For similar stories, visit the [Cancer](#) Topic Guide

Breast screening in the UK is at the centre of renewed controversy after an influential group of British MPs called on the government to provide evidence justifying a planned expansion of the programme. They also want figures provided to women on the pros and cons of screening to be checked by independent experts.

In the UK, breast screening is already offered to women aged between 50 and 70. The government wants to expand the age range to between 47 and 73, and has started a massive clinical trial involving women in the added age bands to evaluate the plan.

Critics say the trial is unethical and must be stopped. They say the women in the younger and older age groups are not being told that the dangers of screening may exceed those of not screening. Indeed, they are not even being clearly told they are taking part in a trial. "At a time when the whole question of screening is thrown into doubt, it seems utterly absurd to extend it," says [Michael Baum of University College London](#), who gave evidence to the UK parliament's science select committee.

Not a no-brainer

Breast screening sounds like it should be a no-brainer: inviting women for regular breast X-rays should catch cancers earlier and save lives.

Yet [a growing body of research](#) suggests that screening may do more harm than good, even in those aged 50 to 70, who are most at risk of breast cancer. The main concerns are false positives and overdiagnosis – detecting and treating small cancers that, if left alone, might in fact regress or grow so slowly as to do no harm. So women are having their breasts removed and radio and chemotherapy unnecessarily, or as Baum puts it, "The commonest cause of breast cancer is screening."

Many countries are now questioning their breast-screening programmes. In 2009, the US Preventive Services Task Force caused outrage when it said [women should be screened when they reach 50, not 40](#) as currently happens in the US.

In the UK, the problem of overdiagnosis has been taken more seriously since the influential [Marmot review of 2012](#). That led to an overhaul of information leaflets for women to make the downsides of screening clearer. They now state that for every 200 women screened, one life will be saved from breast cancer, and three women will be diagnosed with cancer [that would not, in fact, have harmed them](#).

That hasn't satisfied critics, who say the real overdiagnosis figure is higher. Last month, MPs on the [science select committee said in a report](#) that the figures should be checked by the Office

for National Statistics. Such a move would be welcomed by [Susan Bewley](#) of King's College London, who also gave evidence to the committee, because she says it would help ensure the results are unbiased.

Potential risks

The other issue is the proposed expansion, at both ends, of the screening age range. Screening probably carries more risks in these groups: women younger than 50 have denser breast tissue, making false positives more likely, and those over 70 are more likely to die from causes other than breast cancer. That makes it even less likely their life would be saved by having a small cancer removed.

The information given to women taking part in the trial does not mention such issues, points out Bewley. It is just the normal screening leaflet, plus an extra page saying the roll-out is being randomised. "But nowhere does it use the word 'trial'," she says. "This is the biggest-ever human experiment and it's completely unethical."

The trial is being organised by [Public Health England](#). In response to questions from *New Scientist* a spokeswoman said: "This trial has full ethics approval and will prove internationally important to show whether screening in the extended age ranges saves lives."

Critics say ethics approval should never have been granted, and certainly needs to be re-evaluated. The charity HealthWatch says Public Health England released the trial protocol only after three requests under the Freedom of Information Act. It has levelled [many other criticisms](#), too, including that the chief investigator is not a doctor and so is not answerable to the UK's General Medical Council, the doctors' watchdog.

The age extension trial got the go-ahead before the Marmot review came out. Bewley thinks it has too much momentum to be stopped, as it involves 3 million women and runs until 2026. "It's a juggernaut," she says.

Wider breast cancer screening won't be a boon to women

- 13 November 2014
- Magazine issue [2995](#). [Subscribe and save](#)
- For similar stories, visit the [Leaders](#) and [Cancer](#) Topic Guides

CANCER screening sounds like the ultimate in preventive medicine. Spot a tumour early and it is easier to treat and cure.

That's the theory, anyway. But it ignores the potential problem of overdiagnosis – finding tiny tumours that would never have caused any harm, yet get treated aggressively. The big question for any programme is whether the harms outweigh the benefits.

This is answered most clearly for prostate cancer. Most trials show that men who have regular tests live no longer than those who do not. This [evidence](#) stopped the introduction of routine prostate screening in the UK.

There is now a growing body of evidence suggesting that breast cancer screening [has the same](#)

[shortcoming](#). Yet breast screening is an established part of many health systems. Anyone arguing for a rollback is up against entrenched interests.

In the UK, the government is actually considering widening the age range for breast screening despite growing evidence that it puts the age groups concerned at risk (see "[Critics say wider breast screening trial 'unethical'](#)"). The only way to get a reliable assessment of the idea is through a large clinical trial, which the UK is carrying out.

However, the information leaflet given to participants does not tell them they may be at higher risk of overdiagnosis. It does not even clearly state that they are part of a trial, a deficit of informed consent that breaches a basic tenet of medical research. Considering this is the largest ever randomised clinical trial, involving 3 million women, these omissions are shocking.

Attitudes may be changing. Earlier this year, the Swiss Medical Board said [breast screening should cease altogether](#). And a recent [report from UK MPs](#) questioned the age extension.

The UK government does not have to accept the report, but it should use the opportunity to halt the trial until its [many flaws](#) have been addressed. At the very least, the information given to women needs to be corrected so that they are not being misled – or used as unwitting guinea pigs.