Women's Health Academic Centre

Division of Women's Health
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7 November 2015

Dear Anne Mackie

Re: NHS breast screening programme (NHS BSP) and the age-extension trial

We are very pleased to see that cancer and non-cancer screening are now integrated under one roof and under your leadership https://phescreening.blog.gov.uk/2015/06/24/cancer-and-non-cancer-screening-joining-forces/.

We noted the PHE announcement **Guidance: Evidence review criteria: national screening programmes** (23 October, 2015) regarding UK NSC criteria for appraising the viability, effectiveness and appropriateness of any screening programme. The update states that there should be evidence from high quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity, that the benefit should outweigh any harms (e.g. from overdiagnosis), and be cost-effective. We assume the updated guidance refers to overall, rather than disease-specific, mortality for cancer screening. You will be aware of the manifold concerns about breast screening as mortality and morbidity are not reduced. This was true at the time of the Forrest report, and much further evidence has accumulated, including from observational and experimental studies in the intervening time when treatments improved markedly. Although the 2012 Marmot report was used to justify continuing the NHS BSP, those authors did not formally appraise the programme using proper NSC criteria.

Healthwatch-UK has particular concerns about the nationwide cluster-randomised trial of extending the NHS breast screening age range in England http://www.isrctn.com/ISRCTN33292440 that has been running without explicit consent from participants since 2009. Our scientific and ethical concerns are detailed here http://www.healthwatch-uk.org/news/44-concerns-over-age-extension-trial-of-mammography-screening-part-1.html, and particularly relate to the study's credibility, the failure to satisfy GCP and the PI's position. It took an FOI request to obtain a copy of the initial protocol (v1). The trial rationale changed following the 2012 Marmot finding of equipoise and yet continues with an amended protocol (v3). We continue to ask questions about the oversight and respective responsibilities of the researchers, the sponsor (University of Oxford) and the joint funders (PHE, MRC and CRUK). There is no assurance that women are aware they are participating in a human experiment, staff are not trained to explain nor obtain valid informed consent. The trial

has a primary outcome of breast-cancer mortality and will not provide patient level data. Thus, it cannot provide useful information that will inform or change screening policy.

1. If the offer of cancer screening will now be based on NSC criteria will you formally review the validity of the NHS BSP for 50-70 year olds?

2. Given that PHE is, or should be, interested in overall mortality, will the age-extension trial be stopped in view of futility and purposelessness?

With many thanks

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signed on behalf of the following members of Healthwatch-UK:

Michael Baum (founder member)

Debra Bick (deputy chair)

Margaret McCartney (patron)

Mandy Payne (newsletter editor)

Les Rose (trustee)