**Respecting citizens` rights as self-determining individuals in public screening programmes: accessible up-to-date evidence-based information is a prime necessity**

***“…any decision to introduce a screening programme should be based on good-quality evidence not only about its effectiveness but also about its potential for doing harm.”[[1]](#endnote-1)***

Public Health organisations should work to bring benefit to the population they serve, aware always that any medical intervention can potentially cause harm. The balance is critical: causing harm to an asymptomatic citizen who has not sought advice or treatment is a serious matter – very different from that of a patient seeking treatment, weighing potential harms and benefit to determine whether an intervention might be advantageous for them personally. It, of course, presupposes that good quality, reliable information has been made available for them so that they can come to a well informed decision, particularly when they have been invited for screening and especially if that screening is being evaluated in a randomised trial. Yet, within the UK NHS Breast Screening Programme (NHS BSP), we have the scandalous situation that many women are unaware that they participating in the AgeX trial, which is causing numerous iatrogenic harms to citizens for dubious hope of benefit.[[2]](#endnote-2) www.controlled-trials.com/ISRCTN33292440. <https://www.bmj.com/content/365/bmj.l1293> Some participants have neither received information about the trial nor been able to consider giving their consent.

Today, screening interventions targeted at various disease groups of people promoted by Public Health organisations feature highly – a far cry from the single beneficial action in 1854 by St. James parish authorities, of removing the handle from the Broad Street pump to the well which was supplying water to its residents, but bringing cholera and death to that Soho area of London.[[3]](#endnote-3) Screening groups of people to find specific diseases at an early, treatable stage pre-supposes many ideal factors for success and will have the potential to bring benefit to only a small percentage of them, but harm to many. Criteria were first tabulated by Wilson and Jungner[[4]](#endnote-4) in 1968 as a guide to determining the likely value for any specific disease/screening test. Disregarding the Wilson and Jungner and later updated criteria [1, page 45] can bring serious harmful consequences to participating citizens. While patients with a disease may be willing to trade off a degree of harm for the hope of benefit, inflicting harm to citizens-en-masse, without careful categorisation, or opportunity to give consent, is a very different type of iatrogenic harm that surely must be avoided by any Public Health organisation or Ethics Committee. It follows that to fail to enable each individual person to decide whether they wish to participate is unethical and indefensible. It is even more serious if they are unaware that they are a participant.

Let us now consider the UK NHS Breast Screening Programmer (BSP), in operation since 1997/8, with particular reference to the AgeX trial. This is not an insignificant trial: “AgeX is the acronym for the UK government inspired and funded, cluster randomised controlled trial of extending the NHS breast cancer screening age range in England. The trial aims to assess the risks and benefits of extending mammography screening for breast cancer outside the current 50-70 year age range by offering one extra mammogram to women between the ages of 47 and 49 and up to three to those over 70. Announced as “likely to be the largest randomised controlled trial ever undertaken in the world,”[[5]](#endnote-5) during 2010-16 AgeX randomised three million women into the extended age groups and screened one million.[[6]](#endnote-6)” [[7]](#endnote-7)

The shortcomings of this enormous, damaging trial are numerous:

* No systematic reviews were undertaken;
* No impartial review of the protocol was undertaken; it was reviewed `from within` by the Department of Health Advisory Committee on Breast Cancer Screening.
* There was no pilot study.
* The primary outcome measure is death from breast cancer, not overall mortality.[[8]](#endnote-8)
* Reliable evidence of harms was available when the trial was conceived.
* The Marmot Review by an independent panel was published in 2012[[9]](#endnote-9). In 2016 the AgeX recruitment target was raised to 6 million, but this detailed review, which included evidence covering harms and over-diagnosis, was disregarded.
* The trial has no DMEC (Data Monitoring and Ethic Committee). The UK NHS BSP Advisory Committee should have considered the accumulating reliable, robust evidence concerning the harms that screened women were suffering as a consequence of being screened, and/or treated, especially for `cancers` that would not have otherwise have caused them a problem in their lifetime. The chance of suffering known harms had exceeded the potential for benefit, yet participants were not given information about, or access to this evidence, nor apparently was any move made to re-consider the trial`s continuation.
* It appears that the team`s scientific interests when the trial was planned trumped the rights and dignity of women to be allowed to properly consider whether to participate.
* The full, known risks of harm were not conveyed to participants when the patient information leaflet was expanded in 2014,[[10]](#endnote-10) even though robust evidence had been available for some time.
* Decision aids,[[11]](#endnote-11) to help counter the generally pervading public`s overestimation of benefit, are not referred to or recommended. Icon arrays and graphics could also have been used with advantage.
* Incidence of breast cancer increases with age. Thus, a greater number of older women will be identified and treated, although this category of women are less able to tolerate them.
* To expand the age range in the face of increasing evidence that indicates a more targeted approach is preferable, while at the same time incurring extra workload for healthcare staff, extra financial costs, and unnecessarily over-crowding clinics, is inexplicable and unacceptable.

How can such wastage of resources – human and financial – be countenanced, when those in charge of this trial are seemingly impervious to criticism, dismissive of robust evidence of harms; are intent on widening the age range, ignorant of the need for distributive justice; are wasting precious resources and disrespectful of citizens` rights to make their own decisions? How is it that the profession seems to be neither able to stop this juggernaut, nor breach the security of the details of this so-called randomised controlled trial? [2] Meanwhile, other countries have, or are considering de-implementing their screening programmes.[[12]](#endnote-12) [[13]](#endnote-13) How can we tolerate the fact that participants` consent is not sought; that millions of women are being duped? How can the trial`s Ethics Committee possibly justify this iniquity being perpetrated?[[14]](#endnote-14) What is to be done?

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