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Response to Dr Braillon

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LETTERS TO THE EDITOR

Colorectal cancer screening, ethics and evidence-based public policy

Malila *et al*. report on the Finnish colorectal cancer screening programme using a Faecal Occult Blood Test (FOBT)[1], which was launched in 2004 for one-third of the population. Several points merit attention.

The reported uptake is a marked success, increasing from 62% in men and 77% in women for the first round to 68% and 80%, respectively, for the second. This is in marked contrast with other countries. In France, for example, uptake for the first screening round, implemented in 2003 in 23 of 100 districts, only reached 42% (five territories were over 50%, the best reaching 54% and five territories were below 35%).[2] Generalization to all 100 districts only occurred late in 2008, and the second round is still characterized by low participation.

As for every rich country, however, the delay in implementation of the programme should be questioned. Why was there such a delay in responding to and acting on scientific evidence? Data from two randomized controlled trials were available in 1994, and experts published calls for screening as early as 1995.[3] The 2003 recommendation of the European Council[4] for FOBT screening for colorectal cancer in men and women aged 50–74 hopefully challenged this inertia.

Finally, the Finnish programme is ethically questionable. Why did the authorities perform a controlled trial with randomization? This choice deliberately ignored the weight of evidence from trials published since 1995 confirming effectiveness and of reports showing that the effect can be achieved within normal public health care. Why was the control arm a placebo arm? The population in the control arm could have received, at least, an intervention to promote healthy behaviour. This denial of an effective intervention in a population which was not informed is a double breach of the Helsinki declaration which requires, in point 32, 'that patients are not randomized to a clearly inferior treatment'.

Screening programmes have advantages and limitations, and the issue is complex. In 2010, the American Cancer Society recommended that programmes should 'prefer the tests that are designed to find both early cancer and polyps': flexible sigmoidoscopy every five years, or colonoscopy every 10 years, or double-contrast barium enema every five years, or CT colonography (virtual colonoscopy) … 'if you are willing to have one of these more invasive tests'.[5] This was hardly novel; the American College of Gastroenterology in 2000 had endorsed colonoscopy as the preferred strategy. Indeed, for themselves gastroenterologists relied on colonoscopy not on FOBT and recently, President Obama at age 49 underwent virtual colonoscopy.[6] By contrast, in Europe, lay people have no choice but to rely on outdated health policies because policy makers are flying in the face of best evidence and ethics.

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Response to Dr Braillon

Dr Braillon calls for greater accountability in acting on scientific evidence and on reports showing that the effect can be achieved within normal public health care. In fact, Finland was among the first countries in the world to establish organized population-based screening programmes for breast and colorectal cancer after the general evidence from trials was available. We were among the first to know whether screening for breast cancer works as a public health policy (particularistic evidence on decreased mortality from breast cancer) and this will probably also be the case in colorectal cancer screening. Public health policies should be based on both general and particularistic evidence.

There are no studies yet available showing that the effect from trials on colorectal cancer screening can be achieved within normal public health care. Some evidence to the contrary does exist, for example, the programme in France to which Dr Braillon refers. We have not yet seen reports with proper evaluation on the effect on mortality in France.

Dr Braillon is correct – several official bodies have made recommendations, but these are based on different interpretations of the available evidence and on different principles and values in relation to screening programmes. They are not uniform regarding methods of screening and the recommendations *per se* are neither evidence nor proof of effectiveness. There is no direct evidence at present of effectiveness in reducing mortality from colorectal cancer by routine screening with any modality,

and only limited evidence on harms (including cost).

Dr Braillon is also correct that we had no intervention in the control arm. An intervention like health education in this arm would potentially leave open the question of effectiveness. If there were no difference in colorectal cancer mortality between the arms, one would not know whether this was due to similar effectiveness of the interventions or no effect of FOBT (and education). A design which cannot answer the question would be unethical.

We do not think the Helsinki declaration point 32 on inferior treatment applies here. FOBT is generally available and in routine use but promoting indiscriminate use may lead to problems. Limited resources and variation in health-care policies mean that trial results may not always be reproducible, and there are always potential harms from screening. Screening may, for example, promote unfavourable lifestyle changes and these could have a bigger harmful health effect than the small benefit (lower mortality from colorectal cancer) from screening. In several trials the overall mortality was higher in the screening arm than the control arm. No-screening is therefore not an inferior intervention.

To our knowledge there are no organized screening programmes in the US for any cancer site. In much of Northern Europe, by contrast, the public sector provides health care and cancer screening programmes are national and cost-free for the attendee, and based on invitation and particularistic evidence on mortality. The threshold to launch such a programme is higher than the threshold to give a recommendation on indiscriminate screening. This difference explains some, but not all, of the ethical issues.

Comparing Europe with the US is not valid, and raises ethical problems. A public health policy should maintain equity of access, cover the population with more than a theoretical risk (age 49 is far too low for CRC screening), and should be evidence-based. Virtual colonoscopy (or any colonoscopy) has not been studied and the information on effectiveness and harms (like overdiagnosis of preinvasive lesions) is lacking.

The design for colorectal cancer screening programme in Finland with individual randomization was based on several factors: a new programme could not be immediately launched with 100% coverage (not logistically possible, lack of colonoscopy resources etc.). Random allocation of screenees and use of all the available resources maintains equity in the society because everybody has the same *a priori* chance to be screened, and if the programme is not effective or turns out to be harmful, the chance of not being screened is the same for everyone.

We designed the programme, given the available resources, to provide the correct answers to relevant questions as quickly as possible. The programme will show whether screening works and whether it should be continued. It can be modified or stopped if it is not effective or if it is harmful. The general evidence on the expected effect indicates a relatively small reduction in mortality. Most programmes cannot demonstrate such a marginal effect if not randomized at the implementation phase. This is also true in France, where it will probably never be possible to know whether to continue with screening, to modify the programme, or to stop screening.

We therefore believe that our programme maximizes the benefits and minimizes the harms and costs, can be properly evaluated, and is ethically justified.

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How should screeners respond to women's distress about unexpected DCIS uncertainties?

Prinjha *et al.*'s insightful qualitative study demonstrates clearly the anguished responses of women to the predicament of screen-detected ductal carcinoma in situ (DCIS).[1]The findings confirm what has been known since the outset of the screening programme: a diagnosis of DCIS distresses women.[2,3]

However, we disagree with the conclusion that *'Better information about the uncertainties and the rationale for mastectomy as a treatment may help women to make better informed choices and feel more comfortable about their decisions'* as this refers to information and decisions after screening and assumes that the rationale may not be questioned, still less rationally declined.

The results showed four key themes – around the women's understanding of DCIS and its treatment, but also their understanding of routine breast screening and their individual risk of developing breast cancer. We suggest that this is the nub of the difficulties.

When information about the uncertainties and rationale for treating DCIS is given at this late point women are likely to realize that in attending screening they took a gamble whose implications had not been explained and to feel that being 'railroaded' into serious surgery on insufficient evidence is at best questionable, at worst unwarranted. Rather than therapy, which they were led to expect, it is a pre-emptive strike. As difficult as 'Sophie's choice'. Hence the familiar distress.

In light of recent screening mammography research[4–6] it would not be irrational to decline screening to avoid this predicament. Nor would it be irrational to decline treatment when mammograms and further tests have provided no additional information over and above what every woman already knows: that she may or may not, at some unpredictable time, develop life-threatening breast cancer. For those who go on to develop symptoms, increasingly successful treatments can be offered without the traumatic uncertainty. This evaluation cannot be made for