Breast screening: the facts—or maybe not

Peter Gøtzsche and colleagues argue that women are still not given enough, or correct, information about the harms of screening

Three years ago, we published a survey of the information given to women invited for breast screening with mammography in six countries with publicly funded screening programmes.[1] The major harm of screening, which is overdiagnosis and subsequent overtreatment of healthy women, was not mentioned in any of 31 invitations.[1] Ten invitations argued that screening either leads to less invasive surgery or simpler treatment, although it actually results in 30% more surgery, 20% more mastectomies, and more use of radiotherapy[2] because of overdiagnosis.[3 4] Pain caused by the procedure was mentioned in 15 invitations, although it is probably the least serious harm, as it is transient.

Since then, little has changed. Our 2006 article included a box with recommended information and numbers needed to benefit and to harm.[1] Although the information leaflet used in the United Kingdom has since been updated,[5] the contents remain essentially the same. The leaflet has the authoritative title *Breast Screening: the Facts*,[5] suggesting that the information can be trusted. Here, we discuss why it is inadequate as a basis for informed consent and introduce our leaflet, which we think provides the information on the benefits and harms of breast screening that women need to make a rational decision.

Problems with UK leaflet

The revised leaflet emphasises the benefits of screening. The first page leaves no doubt that screening is good for women, with its second heading: "Why do I need breast screening?" Furthermore, it states, "If changes are found at an early stage, there is a good chance of a successful recovery, " and "Around half the cancers that are found at screening are still small . . . This means that the whole breast does not have to be removed." It also tells women that screening saves "an estimated 1400 lives each year in this country" and "reduces the risk of the women who attend dying from breast cancer."

By contrast, little information is given about harms. It states that "some women" find mammography uncomfortable or painful, which becomes "many women" in the summary. The summary also notes that recalls for more investigations "can cause worry." No mention is made of the major harm of screening—that is, unnecessary treatment of harmless lesions that would not have been identified without screening. This harm is well known and acknowledged, even among screening enthusiasts.[3] It is in violation of guidelines and laws for informed consent not to mention this common harm, especially when screening is aimed at healthy people.[3 6 7] The new guidelines from the General Medical Council state: "You must tell patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small."[6] The likelihood of being overdiagnosed after mammography is not very small; it is ten times larger than the likehood of avoiding death from breast cancer.[1 2]

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Another harm is false positive diagnoses. The leaflet notes that about one in every 20 women screened will be recalled for more tests, but does not explain that this 5% rate applies to only one round of screening. The rate of false positive diagnosis after 10 screenings was 50% in the United States and 20% in Norway.[8 9] We now know that the psychosocial strain of a false alarm can be severe and may continue after women are declared free from cancer.[10] Many women experience anxiety, worry, despondency, sleeping problems, and negative impact on sexuality and

Summary from evidence based leaflet

- It may be reasonable to attend for breast cancer screening with mammography, but it may also be reasonable not to attend because screening has both benefits and harms
- If 2000 women are screened regularly for 10 years, one will benefit from the screening, as she will avoid dying from breast cancer
- At the same time, 10 healthy women will, as a consequence, become cancer patients and will be treated unnecessarily. These women will have either a part of their breast or the whole breast removed, and they will often receive radiotherapy and sometimes chemotherapy
- Furthermore, about 200 healthy women will experience a false alarm. The psychological strain until one knows whether it was cancer, and even afterwards, can be severe

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behaviour, and changes in their relationships with family, friends, and acquaintances and in existential values.[10 11] This can go on for months, and some women will feel more vulnerable about disease and will see a doctor more often.[12]

A third harm is caused by radiotherapy of overdiagnosed women. The leaflet states that a mammogram "involves a tiny dose of radiation, so the risk to your health is very small." The rate of overdiagnosis was 30% in randomised trials of screening and 50% in observational studies.[2 13 14] We therefore believe it is misleading to assure women that the radiation dose from the mammogram is tiny, without telling them that the much bigger dose used in radiotherapy is harmful when given to healthy people. Comparison of left sided with right sided irradiation suggests that radiotherapy may double the mortality from heart disease and lung cancer.[15] Technological improvements may have diminished these harms to some extent, but they are still important.

The summary implies that screening leads to fewer mastectomies. This is incorrect. Screening led to 20% more mastectomies in randomised trials[4] and observational studies have confirmed that the number of mastectomies increases when screening is introduced.[2] These initial increases are not compensated for by reduced rates among older women who are no longer screened (unpublished national data, Danish National Board of Health).

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Carcinoma in situ is not mentioned in the leaflet, although it constitutes about 20% of the diagnoses made at screening in the UK. Fewer than half of the cases progress to invasive cancer, and 30% are treated with mastectomy.[16] A patient representative has described her experience of gaining this information as trying to "uncover a closely guarded state secret."[4]

There are no reservations in the leaflet about screening older women, only a scare that the breast cancer risk increases with age, although it has not been shown that screening these women decreases their risk of dying from breast cancer. Furthermore, the problem with overdiagnosis becomes more pronounced, and the likehood of gaining any benefit smaller, due to competing risks of death.

Finally, it has not been proved that screening saves lives. There is an inevitable bias in assessment of cause of death that can be particularly difficult when women have more than one cancer.[2] Trials show that breast screening does not decrease total cancer mortality. The relative risk was 1.02 (95% confidence interval 0.95 to 1.10) in the two most reliable trials and 0.99 in the others, and there is no reliable evidence that screening decreases total mortality,[2] although half a million women participated in the screening trials. This indicates that the benefit of screening is likely to be smaller than generally perceived.

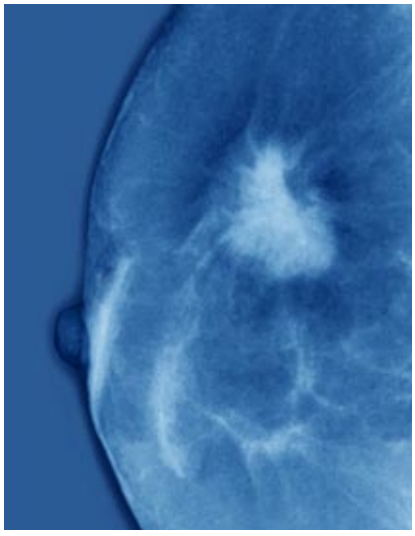
Alternative leaflet

We have written an evidence based leaflet (see bmj.com) to help women decide about breast screening. As recommended,[4] it describes benefits and harms in numbers that can readily be understood and uses the same denominator throughout: 2000 women screened every two years for 10 years.

We tested draft versions among general practitioners in Denmark, Norway, and Sweden belonging to the Nordic Risk Group Network and among lay people, which led to considerable improvements. A physician noted that it was unbalanced because we had listed several harms but only one benefit. We therefore tried to list more benefits, but realised that there is only one important benefit, the reduction in breast cancer mortality. It is often claimed that a normal mammography result reassures women that they are healthy. But most women will feel healthy before they are invited to screening, and the invitation may also cause insecurity as well as false security because about half of the breast cancers that require treatment are found between screening rounds.[3] Therefore, screening creates security, insecurity, and false reassurance.

The box gives the summary from the leaflet. We hope it provides sufficient information to enable women, together with their family and general practitioner, to decide whether

to participate.[4] The leaflet was distributed to general practitioners and gynaecologists in Denmark in March 2008. It is available in English and Danish and can be downloaded from bmj.com, screening.dk, or cochrane.dk. It will be translated into Icelandic, Norwegian, Swedish and Finnish and we aim to update it when necessary.



The one sided propaganda about breast screening has resulted in misconceptions about its effects

Consequences of imbalance

The one sided propaganda about breast screening is a global phenomenon that has resulted in misconceptions about its effects.[1] A survey of American and European women[17] found that 68% believed screening reduced their risk of contracting breast cancer, 62% that screening at least halved mortality, and 75% that 10 years of screening saved 10 of 1000 participants (an overestimate of 20 times[2]). Another study showed that only 8% were aware that participation can harm healthy women[18] and that 15% believed their lifetime risk of contracting the disease was more than 50% (an overestimate of five times).

The UK National Screening Committee agreed in 2000 that the purpose of information was not to recruit women but to allow them to choose whether to participate,[4] but this decision has not had any effect on the information provided.[5] New evidence that shows less benefit and substantially more harm from screening than previously thought has largely been ignored.[1 5] We believe that if policy makers had had the knowledge we now have when they decided to introduce screening about 20 years ago, when nobody had published data on overdiagnosis or on the imbalance between numbers of prevented deaths from breast cancer and numbers of false positive screening results and the psychosocial consequences of the false alarms, we probably would not have had mammography screening.

Women taking tests continue to experience morbidity and regret because they found out many of the harms of screening from experience.[19] It may be too late to start asking questions on arrival to the screening unit, as the UK leaflet suggests.[5] There is also a conflict of interest when those who provide the information are responsible for the success of the screening programme.[1] High participation rates are pivotal, and information about harms may deter women from participation.

The question of whether the benefits of screening outweigh the harms is a value judgment that needs to be made by invited women.[19] To allow this to happen, the responsibility for the screening programmes must be separated from the responsibility for the information material,[1] and information materials should be carefully tested among general practitioners and lay people.

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1 Jørgensen KJ, Gøtzsche PC. Content of invitations to publicly funded screening mammography. *BMJ* 2006;332:538-41.
2 Gøtzsche PC, Nielsen M. Screening for breast cancer with mammography. *Cochrane Database Syst Rev* 2006;(4):CD001877.
3 Vainio H, Bianchini F. *IARC handbooks of cancer prevention. Vol 7: breast cancer screening*. Lyon: IARC Press, 2002.
4 Raffle A, Gray M. *Screening: evidence and practice*. Oxford: Oxford University Press, 2007.
5 Department of Health, NHS Cancer Screening Programmes. *Breast screening: the facts*. 2006. www.cancerscreening.nhs.uk/breastscreen/publications/ia-02.html..
6 General Medical Council. *Consent: patients and doctors making decisions together*. London: GMC, 2008. www.gmc-uk.org/guidance/ethical_guidance/consent_guidance/index.asp.
7 Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L, eds. *European guidelines for quality assurance in breast cancer screening and diagnosis*. 4th ed. Luxembourg: Office for Official Publications of the European Communities, 2006.
8 Elmore JG, Barton MB, Moceri VM, Polk S, Arena PJ, Fletcher SW. Ten-year risk of false positive screening mammograms and clinical breast examinations. *N Engl J Med* 1998;338:1089-96.
9 Hofvind S, Thoresen S, Tretli S. The cumulative risk of a false-positive recall in the Norwegian breast cancer screening program. *Cancer* 2004;101:1501-7.
10 Brodersen J, Thorsen H, Kreiner S. Validation of a condition-specific measure for women having an abnormal screening mammography. *Value in Health* 2007;10:294-304.
11 Brodersen J. *Measuring psychosocial consequences of false-positive screening results - breast cancer as an example*. Department of General Practice, University of Copenhagen. 2006. http://cms.ku.dk/sund-sites/ifsv-sites/ifsv-inst/ominstituttet/afdelinger/almen_medicin/medarbejdere/publicationdetail/?id=1109837.
12 Barton MB, Moore S, Polk S, Shtatland E, Elmore JG, Fletcher SW. Increased patient concern after false-positive mammograms: clinician documentation and subsequent ambulatory visits. *J Gen Intern Med* 2001;16:150-6.
13 Zahl P-H, Strand BH, Mahlen J. Breast cancer incidence in Norway and Sweden during introduction of nation-wide screening: prospective cohort study. *BMJ* 2004;328:921-4.
14 Jørgensen KJ, Gøtzsche PC. Overdiagnosis in publicly organised mammography screening programmes: systematic review of incidence trends. *BMJ* (in press).
15 Darby S, McGale P, Taylor C, Peto R. Long-term mortality from heart disease and lung cancer after radiotherapy for early breast cancer: prospective cohort study of about 300 000 women in US SEER cancer registries. *Lancet Oncol* 2005;6:557-65.
16 Department of Health, NHS Cancer Screening Programmes. *Screening for breast cancer in England: past and future*. 2006. www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp61.html.
17 Domenighetti G, D'Avanzo B, Egger M, Berrino F, Perneger T, Mosconi P, et al. Women's perception of the benefits of mammography screening: population-based survey in four countries. *Int J Epidemiol* 2003;32:816-21.
18 Schwartz LM, Woloshin S, Fowler FJ Jr, Welch HG. Enthusiasm for cancer screening in the United States. *JAMA* 2004;291:71-8.
19 Thornton H, Edwards A, Baum M. Women need better information about routine mammography. *BMJ* 2003;327:101-3.

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