

Analysis and comment

Public health

Content of invitations for publicly funded screening mammography

Karsten Juhl Jørgensen, Peter C Gøtzsche

The benefits and harms of screening for breast cancer are delicately balanced and women should decide for themselves, on an informed basis. Do the invitations give enough information to enable this?

See also p 499

Nordic Cochrane Centre, Rigshospitalet Department 7112, Blegdamsvej 9, DK-2100 Copenhagen, Denmark
Karsten Juhl Jørgensen *research fellow*
Peter C Gøtzsche *director*

Correspondence to: K J Jørgensen kj@cochrane.dk

BMJ 2006;332:538-41

Invitations to screening mammography play a central part in the process of obtaining informed consent. It is the only source of information distributed to all potential participants. Other sources, such as pamphlets and websites, have been shown to be information poor and biased in favour of participation,^{1 2 w1 w2} and information from the media and doctors is likely to vary and be unevenly distributed. We examined mammography invitations from English speaking and Scandinavian countries with publicly funded screening to assess whether they provide sufficient information to enable women to make an informed decision.

Information versus high uptake

When a society decides to offer cancer screening, eligible citizens need to be made aware of the programme. A letter of invitation is a common approach, and it seems obvious to use this letter to provide balanced information about benefits and harms of screening, particularly since there is international consensus that participation in cancer screening should be based on informed consent.^{3 w3 w4} However, in countries with publicly funded screening, those responsible for the

success of the programme are also those who provide the information. Herein lies a potential conflict of interest. High participation rates are pivotal to any screening programme, but information about potential harms may deter women from participation.

What do women believe?

Women generally exaggerate the benefits and are unaware of the harms of screening.⁴⁻⁶ The authors of a study of American and European women⁴ raised doubts about informed consent procedures since 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, which is 10 times the most optimistic estimates.⁷⁻⁹ Other studies have shown that only 8% of women were aware that participation has the potential to harm healthy women,⁵ that 15% believe their lifetime risk of contracting the disease is more than 50% (an overestimate of about 5 times),⁶ and that one third think screening detects more than 95% of breast cancers.^{w5}

Assessment of invitations

We collected invitations to mammography screening from Australia, Canada, Denmark, New Zealand, Norway, Sweden, and the United Kingdom. These countries all have publicly funded screening programmes that are nationally or regionally coordinated and use languages we can read. We requested letters that invited women for the first time including any enclosed pamphlets, letters to non-responders, and invitations to subsequent screening rounds. We focused on the initial invitation, which is most commonly sent out as women turn 50 years of age. We contacted organising units by email, telephone, or post and made three requests in case of non-response.



GATROPHAN/REX

How many women understand the full implications of screening?

References w1-w11 and details of invitations are on bmj.com



Material was collected between October 2004 and February 2005.

We recorded whether a date of appointment was issued in the invitation, whether a reminder letter or other means of contact was used for non-responders, whether suggestive headlines or appeals for participation were used, and whether regular breast self examinations, clinical breast examinations, or both were recommended, as an additional check on whether the information was evidence based.¹⁰ We evaluated the invitations independently and settled any discrepancies by discussion. We used the same checklist of 17 information items on benefits and harms as in our previous study of websites,⁷ most of which have been used in other studies of information materials.^{1-6,11}

We identified 51 coordinating units and 33 (65%) responded. The unit in southern Australia declined to supply a sample as it was revising its invitation, and Nova Scotia, Canada, did not issue invitations but used public advertising. Thus, we obtained samples from 31 areas, including all seven countries. For Norway and the UK, we evaluated a national sample letter. In the UK, this letter may be modified locally, but the accompanying pamphlet, which contains the bulk of the information, is the same. The Norwegian letter and pamphlet are used nationwide. The response rate was lower for Sweden than for other countries (9/22 regions), but this is unlikely to have influenced our overall findings because the information varied little among those that responded.

How are women invited?

Since the wording and contents differed little within each country, our main emphasis is on the national results (see table on bmj.com). Twenty one invitations (68%), at least one from each country, gave an appointment date, but in New Zealand women receive a letter only after registering with the programme. Reminder letters were used in 18 of 31 areas (58%) but not in Sweden or the UK. In New Zealand, women who do not attend their appointment are telephoned, and in Western Australia and some areas of New Zealand, a letter is sent to general practitioners informing them about non-responders and asking them to discuss this with the woman at the next consultation. These national differences limit the applicability of our results to countries we did not include, in particular countries where screening is a private enterprise.

What do the invitations contain?

The invitations included a median of 2 of the 17 possible information items in our survey, ranging from none in Sweden to six in New Zealand. A pamphlet was included with 20 invitations (65%), but only in one of nine invitations in Sweden.

Thirty invitations (97%) mentioned the main benefit of screening, a reduction in breast cancer mortality, but only seven (three countries) gave the size of the benefit and they all described it as a relative risk reduction rather than an absolute risk reduction or the number needed to screen. The effect of screening on total mortality was not mentioned. In contrast, no invitation mentioned the major harm of screening, overdiagnosis and subsequent overtreatment.

Six invitations (five countries) argued that screening leads to less invasive surgery and four additional invitations (one additional country) that it leads to simpler treatment. None of the invitations noted the uncertainties related to treatment of carcinoma in situ or the increased use of surgery and radiotherapy arising from overdiagnosis.

The most commonly mentioned harm was pain associated with the procedure (15 invitations (48%), six countries), but it was downplayed in eight—for example, “Any discomfort should only last a few seconds” (Breast-Screen Western Australia). The lifetime risk of developing breast cancer was noted in 10 invitations (32%, six countries) and estimates varied from 1 in 9 to 1 in 13.

Recall rates for further examinations appeared in six invitations (19%), but as the risk in each screening round, not the accumulated risk. After 10 screens, the accumulated risk of recall is about 50% for American women¹¹ and about half as much for European women.¹² About a quarter of these women will have a biopsy or fine needle aspiration.⁹ A false positive result can have a profound psychological effect on women and their families because it raises the suspicion of a potentially life threatening disease.¹³

Seven invitations mentioned screening sensitivity, but five were misleading. For example, the Manitoba pamphlet states that “about 1 out of every 10 breast cancers cannot be seen on a mammogram,” a 90% detection rate. This obscures the fact that many, indeed the most dangerous, cancers are detected in the intervals between screening rounds.³ Interval cancer rates of up to 50% are deemed acceptable with biennial screening according to European guidelines.¹⁴ Neither specificity nor positive predictive value was mentioned.

Fifteen invitations (48%) recommended regular breast self examination, clinical breast examinations, or both. This is despite evidence that self examination leads to a doubling in biopsy of benign growths and probably has no mortality benefit¹⁰ and the lack of evidence for an effect of clinical breast examinations.^{3,9}

Appeals for participation appeared in only one of nine letters in Sweden, but in 17 of the remaining 22—for example, “We strongly recommend that you use this free service” (Northern Territory, Australia). Seven reminder letters had stronger pleas than the first letter (box 1).

Nineteen pamphlets (95%) had suggestive headlines, such as, “Have a screening mammogram, it may save your life” (Western Australia) and “Why is having a breast screen a good idea?” (New South Wales, Australia).

Problems with current practice

Although it is good news that the invitations often included an information pamphlet, the focus on the benefits of screening is problematic. The benefits were framed positively, avoiding absolute risk reductions and number needed to treat, which are easier to understand and provide more realistic expectations.¹⁴ The reduction in breast cancer mortality was given as 25-30%, although recent systematic reviews have either doubted the effect⁸ or suggested relative risk reductions of 15%-21%.^{9,15} These estimates do not convey that they apply only to the period when women are screened and are not a reduction in lifetime risk.

Box 1: Excerpts from information material

Invitational letters

"We have reserved a time ... If the time is very inconvenient, we ask you to contact the mammography screening centre as soon as possible" [our translation]—Funen, Denmark

"During the past two years, over 340 000 Queensland women have benefited from taking part in the BreastScreen Queensland Programme" [this refers to the number of participants; less than 0.1% of those would have benefited]

"You can take a positive step to decrease your own risk, and help us achieve our goal, by deciding to take part" [clear conflict of interest]—Northern Territory, Canada

"I am writing to personally invite you" [inappropriate use of familiarity]—Vancouver

Letters to non-attenders

"I do not wish to participate in the examination due to the following reason: _____" (return slip) [Is it acceptable to demand a reason for declining participation in something the woman didn't ask for?]-Funen, Denmark

"If you would like to avoid participation, we ask you to fill out a form. You obtain this form by calling the breast-diagnostic centre" [our translation; some work is required to avoid further invitations]—Norway

"Some of these studies have been going on for 30 years and none have found any serious side effects from the mammography" [this is wrong because overdiagnosis is a serious harm]—New South Wales

"I am concerned that you have not yet responded to our recent invitation for a screening mammogram (breast x ray) ... Every year in NSW about 3000 women develop breast cancer and about 900 die from the disease" [Paternalistic, and tells non-attenders that they are behaving irresponsibly]

Pamphlets

"There has been a 26% increase in breast cancer cases in the last ten years" [scaring and misleading—this is the level of overdiagnosis expected with screening over the 10 years this programme had been operating]—Ontario

"Research has shown that regular screening mammograms can lower deaths in women 50 to 69 years of age by 1/3" [the risk of dying (total mortality) is reduced by 0.1% at most]—Manitoba

"The benefits of screening far outweigh the risks of any harm from the breast screen" [subjective statement; this judgment should be left to the women]—Queensland

The most important harms, overdiagnosis and overtreatment, were not mentioned and other important harms were often either omitted or downplayed. The estimated level of overdiagnosis, 30% in the randomised trials,⁸ is supported by large epidemiological studies that have suggested 40-60%.¹⁶⁻²⁰ Carcinoma in situ is a special case as it is rarely detected without screening and represents about 20% of all screen detected cancers.³ Little is known about its natural course, but autopsy studies indicate that many lesions do not progress.²¹ Because it is impossible to tell which lesions will become invasive, all are treated, often with mastectomy and radiotherapy.^{8 9}

Overdiagnosis led to screening programmes for neuroblastoma in children being stopped^{w6} and is a

main reason why screening for prostate and lung cancer is generally discouraged.²² Very few women are aware that screening can detect non-progressive cancer,²³ and probably even fewer know that invasive cancer can sometimes regress spontaneously.^{w7} Many will falsely believe their lives have been saved by screening, when in fact they have only been physically and psychologically harmed.

Participation rates increase when there is a pre-assigned date of appointment,^{3 24} but we find this approach problematic as it bypasses the informed consent step and gives the impression that participation is a public duty. Information material should convey the message that a decision not to attend mammography screening can be based on sound reasoning and is not irresponsible, as is currently believed by about 75% of 55 year old Americans.⁵

Fear of cancer seems to increase participation in breast cancer screening,^{w8} and the frequent mention of lifetime risk of developing breast cancer in the information could scare some women to participate without considering the harms, especially as these were so rarely mentioned.

More comprehensive information will lead to more women declining to be screened.^{w9} Uptake rates in Sweden are high, 78-84%,³ which may be related to the fact that the invitations contain little information apart from a date of appointment and explanations of practical matters such as transport and payment of a small fee.

Implications

Informed consent cannot be achieved solely through information in invitations. It is a process that should include a discussion with a general practitioner, as preferred by 88% of Swiss women.^{w10} It is not reasonable to assume that participants have been adequately

Box 2: Key elements in information leaflets

Main benefits and harms, assuming a 15% reduction in breast cancer mortality and overdiagnosis of 30%
If 2000 women are screened regularly for 10 years:

- 1 woman will avoid dying from breast cancer
- 10 healthy women, who would not have been diagnosed without screening, will have breast cancer diagnosed and be treated unnecessarily; 4 of these will have a breast removed, 6 will receive breast conserving surgery, and most will receive radiotherapy
- 1800 will be alive after 10 years; without screening 1799 will be alive.⁸

Other main points

Of 2000 women (in Europe) who participate in 10 rounds of screening

- 500 will be recalled for additional investigations because cancer is suspected; about 125 will have a biopsy⁹
- 200 will experience psychological distress for several months related to a false positive finding⁸

Screening can provide false reassurance. Up to 50% of cancers among women in screening programmes are detected between two screening rounds,^{w1} and these interval cancers are the most dangerous

Mammography is painful for about a third of women^{w11}

Summary points

Conflict of interest exists for publicly funded screening since organisers want a high uptake

No invitations contain information about the major harms of screening

Most invitations use pre-specified appointments and persuasive wording

The information sent to women needs to be more balanced

Harms and benefits should be presented in more easily understandable ways

informed about important harms through other sources. We believe that the information included with invitations should be more balanced, using absolute numbers to describe the likelihood of benefits and harms,¹⁹ and applying to the same time span if possible (box 2). Furthermore, we suggest that the responsibility for the programmes should be separated from the responsibility for the information material and that consumer groups be involved in the process of developing balanced information material.

We thank those who supplied material, Hazel Thornton for contact details for the UK screening programme, and Kay Dickersin for comments on our manuscript.

Contributors and sources: We have previously evaluated information on mammography screening on websites and PCG was involved in a systematic review of the breast screening trials, which questioned the value of screening. Both authors contributed to conceiving the project. The draft protocol was written by KJJ and revised by PCG. KJJ collected the invitations and wrote the first manuscript. Both authors extracted data and contributed to the interpretation and final manuscript. Both are guarantors.

Competing interests: None declared.

- 1 Slaytor EK, Ward JE. How risks of breast cancer and benefits of screening are communicated to women: analysis of 58 pamphlets. *BMJ* 1998;317:263-4.
- 2 Jørgensen KJ, Gøtzsche PC. Presentation on websites of possible benefits

- and harms from screening for breast cancer: cross sectional study. *BMJ* 2004;328:148.
- 3 Vainio H, Bianchini F. *IARC handbooks of cancer prevention. Vol 7: breast cancer screening*. Lyons: IARC Press, 2002.
 - 4 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.
 - 5 Schwartz LM, Woloshin S, Fowler FJ Jr, Welch HG. Enthusiasm for cancer screening in the United States. *JAMA* 2004;291:71-8.
 - 6 Barratt AL, Cockburn J, Redman S, Paul C, Perkins J. Mammographic screening: results from the 1996 national breast health survey. *Med J Aust* 1997;167:521-4.
 - 7 Nyström L, Rutqvist LE, Wall S, Lindgren A, Lindqvist M, Ryden S, et al. Breast cancer screening with mammography: overview of Swedish randomised trials. *Lancet* 1993;341:973-8.
 - 8 Olsen O, Gøtzsche PC. Cochrane review on screening for breast cancer with mammography. *Lancet* 2001;358:1340-2. <http://image.thelancet.com/extras/fullreport.pdf> (accessed 8 Feb 2006).
 - 9 Humphrey LL, Helfand M, Chan BK, Woolf SH. Breast cancer screening: a summary of the evidence for the US Preventive Services Task Force. *Ann Intern Med* 2002;137:347-60.
 - 10 Kösters JP, Gøtzsche PC. Regular self-examination or clinical examination for early detection of breast cancer. *Cochrane Database Syst Rev* 2003;(2):CD003373.
 - 11 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.
 - 12 Smith-Bindman R, Chu PW, Miglioretti DL, Sickles EA, Blanks R, Ballard-Barbash R, et al. Comparison of screening mammography in the United States and the United Kingdom. *JAMA* 2003;290:2129-37.
 - 13 Aro AR, Pilvikki Absetz S, van Elderen TM, van der Ploeg E, van der Kamp LJ. False-positive findings in mammography screening induces short-term distress—breast cancer-specific concern prevails longer. *Eur J Cancer* 2000;36:1089-97.
 - 14 Fahey T, Griffiths S, Peters TJ. Evidence based purchasing: understanding results of clinical trials and systematic reviews. *BMJ* 1995;311:1056-9.
 - 15 Nyström L, Andersson I, Bjurstram N, Frisell J, Nordenskjöld B, Rutqvist LE. Long-term effects of mammography screening: updated overview of the Swedish randomised trials. *Lancet* 2002;359:909-19.
 - 16 Gøtzsche PC. On the benefits and harms of screening for breast cancer. *Int J Epidemiol* 2004;33:56-64.
 - 17 Zahl PH, Strand BH, Mæhlen J. Incidence of breast cancer in Norway and Sweden during introduction of nationwide screening: prospective cohort study. *BMJ* 2004;328:921-4.
 - 18 Douek M, Baum M. Mass breast screening: Is there a hidden cost? *Br J Surg* 2003;90:44-5.
 - 19 Barratt A, Howard K, Irwig L, Salkeld G, Houssami N. Model of outcomes of screening mammography: information to support informed choices. *BMJ* 2005;330:936-8.
 - 20 Jonsson H, Johansson R, Lenner P. Increased incidence of invasive breast cancer after the introduction of service screening with mammography in Sweden. *Int J Cancer* 2005;117:842-7.
 - 21 Welch HG, Black WC. Using autopsy series to estimate the disease "reservoir" for ductal carcinoma in situ of the breast: how much more breast cancer can we find? *Ann Intern Med* 1997;127:1023-8.
 - 22 Welch HG. *Should I be tested for cancer? Maybe not and here's why*. Los Angeles: University of California Press, 2004.
 - 23 Schwartz LM, Woloshin S, Sox HC, Fischhoff B, Welch HG. US women's attitudes to false positive mammography results and detection of ductal carcinoma in situ: cross sectional survey. *BMJ* 2000;320:1635-40.
 - 24 Bonfill X, Marzo M, Pladevall M, Martí J, Emparanza JI. Strategies for increasing women participation in community breast cancer screening. *Cochrane Database Syst Rev* 2001;(1):CD002943.

(Accepted 1 December 2005)

Hoax bomb calls and psychiatry

Nowadays in Britain, it is not uncommon to read or hear a news headline about a person "arrested and charged in connection with a hoax telephone call warning of a bomb." Such hoaxers are often labelled insensitive, uncaring, or psychopaths, but a patient I recently saw in my clinic has made me see this phenomenon differently.

She started by saying how anxious she was to be in the city centre, given recent bomb alerts. I empathised with her and shared my not dissimilar concerns. She volunteered several possible explanations for the London bombings of July 2005—the Iraq war, anti-Western sentiments, Islamic fundamentalism, and so on. She added that her thyroid gland was swollen, that she was emitting a bile-like substance from her "waste pipes," and that she was in the process of designing a spacecraft for the salvation of humanity. A clear picture of psychosis emerged.

She continued by saying that she had seen a suspicious car abandoned in the hospital car park. It was red and very clean,

which had led her to believe it belonged to a suicide bomber, as "they wash their blood and conscience off, don't they? So, it's always clean. Maybe, I should have called the police, but I didn't."

Some patients with psychotic disorders may incorporate recent public events into their existing delusional belief systems and occasionally even act out these delusions. My patient, among other delusions, held bizarre beliefs about suicide bombers (triggered by recent events) and nearly acted on this delusion by calling the police. We should consider such a possibility before blaming all people who make hoax calls. Their behaviour may be a manifestation of underlying psychopathology. Perhaps, all such calls should lead to the perpetrator being required to submit to mental health assessment.

Sanju George *specialist registrar in psychiatry, Queen Elizabeth Psychiatric Hospital, Edgbaston, Birmingham*
(sanju.george@talk21.com)