

Are women getting relevant information about mammography screening for an informed consent: a critical appraisal of information brochures used for screening invitation in Germany, Italy, Spain and France

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Background: The aim was to find out if information brochures on mammography screening in Germany, Italy, Spain and France contain more information to facilitate informed consent than in similar studies carried out over the last few years in Sweden, Canada, USA and the UK, countries with different medical cultures. **Methods:** We generated a list of essential information items on mammography screening for the purpose of informed consent. We mostly used the same items of information as had been used in previous studies and analysed the information brochures of major national initiatives in Germany and France, and three brochures each from regionalized programmes in Italy and Spain. We cross-checked which of our items were covered in the brochures and if correct numbers were given. **Results:** We found that the information brochures contained only about half of the information items we defined. Six of the eight brochures mentioned the reduction in breast-cancer fatalities. Four of the eight provided information on false positives, and four of the brochures highlighted the side-effects of radiation. The information on side-effects and risks provided by the brochures was generally of poor quality, and none of them referred to over diagnosis. When numbers were given, they were only indicated in terms of relative numbers. **Conclusion:** The information brochures currently being used in Germany, Italy, Spain and France are no better than the brochures analysed some years ago. Our results suggest that the providers of mammography screening programmes continue to conceal information from women that is essential when making an informed decision.

Keywords: information brochures, informed consent, mammography screening.

Introduction

In countries where mammography-screening programmes have been systematically implemented for more than a 10-year period (the UK, Canada and Sweden), assessments have shown them to be relatively effective, reducing breast cancer mortality rates by around 20%^{1,2} provided that a 70% participation rate among eligible women was accomplished. The programmes in these countries enjoy good reputations and ongoing efforts are being made to sustain high participation rates.³

However, the suggestion has been put forward that even under ideal conditions statistically, the benefit for individual women taking part in these programmes is negligible. For example, if 2000 women aged between 50 and 69 years are screened every second year over a 10-year period, only between one and two of these women will be successfully treated for breast cancer.^{1,4}

Making an informed decision is one of the basic principles of patient care.⁵ To enable women to make an informed

decision concerning their participation in a screening programme, they should have sufficient information about the benefits provided by these programmes both on a public-health level and with regard to their own individual benefits and risks.^{3,6}

For the majority of women invited to take part in screening programmes, brochures and leaflets are the most important sources of information. In most European countries these leaflets accompany the invitation letter sent out by the registration centres.

Information brochures used in English-speaking and Scandinavian countries were analysed in 2003 and 2006 in terms of the quality and comprehensiveness of the information they provided to women.^{7–9} Similar studies took place on brochures from Italy,¹⁰ Austria,¹¹ and from Germany in 2003.¹² At that time each state in Germany had its own leaflet and these differed from the one we analysed. The analysis revealed that none of the brochures provided the necessary information to make an informed choice. Today, Germany has just one leaflet for the whole country, which we will analyse in this study.

The reasons for which we carried out a further analysis of the brochures were:

(i) we hoped that over time brochures would have improved and (ii) we have selected brochures from countries where a more personalized culture of medical care exists—in the hope that this leads to more accurate information. For this purpose, we analysed the brochures in use in Germany and countries speaking romance languages, i.e. France, Spain and Italy.

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Methods

Included brochures

In Germany and France 'national' information brochures on mammography screening are issued on a nationwide basis by centralized organisations. However, in Italy and Spain, brochures are distributed by regional bodies. Therefore, we decided to include three separate brochures from each of these countries which fulfilled the following criteria: (i) issued by an authorized organization (e.g. statutory body); (ii) distributed on a regional (as opposed to local) level and (iii) available to a population of >1 million inhabitants. The names of the selected brochures are derived from their region of origin.

Assessment criteria

We used the criteria essential for informed choice as defined by Jørgensen and Goetzsche^{7,13} to compare the results of our analysis with the results from a number of previous studies.

The 15 criteria that we employed are listed below with additional information on their relevance for mammography screening.

Expressing the benefits of mammography screening (1): The benefits are often overestimated by women^{14,15} and therefore should be outlined clearly. It can be measured by the *reduction of breast cancer mortality due to screening (2)*. Participation in mammography screening (by women aged 50–69, every 2 years) would lead to a 20% reduction in relative terms in breast cancer mortality rates (relative risk reduction, RRR)—assuming a participation rate of about 70% of the target population.^{1,2} However, any data outlining relative risk reduction often lead to an overestimation of the benefits by the participants. Therefore any benefits should also be expressed in terms of *absolute risk reduction (ARR) (3)*: A 20% RRR of death from breast cancer in a population of 10 000 screened patients can amount to a reduction not only from 1000 to 800 fatalities but also from 100 to 80 in the same population. The ARR is 200 per 10 000 in the first case, and 20 per 10 000 screened in the second. It provides clear answers to any questions from the patients on the benefits of taking part in a screening programme.

In mammography screening of women aged 50–69 in 2-year intervals, the ARR is between 0.5 and 1 per every 10 000.

Another way to illustrate the absolute benefit is by identifying *the number needed to screen (NNS) (4)*. In other words, how many women have to be screened to save one from dying of breast cancer. It is the reciprocal value of the ARR. In real terms (see above) this means: the NNS is between 1/20 000 and 1/10 000. In other words: If 2000 (or 1000 respectively) women aged between 50 and 69 are screened every 2 years over a period of 10 years, one (or two respectively) women will be saved from dying of breast cancer.^{16,17}

Any reduction in the overall mortality rates (5) due to mammography screening will include any mortality caused by conditions or circumstances aside from breast cancer. There is no evidence of any reduction in overall mortality rates as a result of screening, not even of an appreciable reduction of overall cancer mortality. On the contrary, according to some authors any potential reduction in mortality rates may be nullified by instances of overdiagnosis^{2,18} which lead to an increase in mortality rates caused by unnecessary surgery, chemotherapy and radiotherapy.^{19,20}

Rate of pathological result from screening (6): During each round of screening, about 7% of patients will be called back for a further diagnostic investigation. This amounts to about

25% over a 10-round cycle, e.g. of 1000 women taking part in the programme over the whole screening period, around 200–250 women will be recalled at some point. Of these 20–25 (about 10%) will be referred for biopsy, and of every ten women referred for biopsy, about four will have cancer and six will not.¹⁶ Benefits and harms should be presented at the same reference parameter, e.g. related to the whole screening period.

Even if the *specificity (7)* of mammography screening is about 95%, which sounds impressive, it cannot hide the fact that most of the seemingly positive findings are not true positives. This can be explained by the fact that the screening takes place within a group with low prevalence (3–5 per 1000 screened) of cancer. *False positives (8)* may lead to unnecessary interventions, such as follow-up mammograms, biopsies or surgery, and to psychological and physical distress. And sometimes in the assessment of a false-positive result from mammography another false-positive finding may result—leading to surgery, radiation and chemotherapy.¹⁸

Sensitivity of screening (9) is commonly measured by the incidence of *interval cancer (10)*. In cases where cancer is detected during an interval between two mammography screenings, the woman would gain no benefit from participating in the programme. Even if we acknowledge that the technology of mammography screening has improved over the last few years, the incidence of interval cancer is still relatively high. The rate of incidence varies—depending on study and definition, but is somewhere between 25 and 40% based on a 2-year screening interval.^{16,17,21}

The incidence of interval cancer may be affected by overdiagnosis. High rates of over diagnosis may in fact reduce the percentages identified between screening rounds and can therefore lead to the sensitivity of the programme being overestimated.

Early detection does not necessarily correspond with a reduction in mortality rates or an increase in the quality of life. If metastases have occurred prior to detection, the survival time will not be prolonged, but the woman will be aware of the illness earlier and will receive treatment. This is often futile, and will adversely affect her quality of life from an earlier point in time.

Information on *lead-time bias (11)* is an important part of informed consent because it gives an impression of how early the diagnosis will be found.²¹

Overdiagnosis (12): This has to do with how many ductal carcinoma *in situ* (DCIS), or indeed early carcinoma, are discovered that never had any clinical relevance.²² This can be down to the fact that DCIS can regress to normal levels or, as in the early stages of breast cancer, that a person is dying from some other condition before cancer reaches a critical stage. It is estimated that of those cancers diagnosed using mammography between 30% (Welch) and 50% (Jorgensen) are a result of overdiagnosis.^{23,24} But overdiagnosis will also lead to an *increase in surgery and radiotherapy (13)* among women who actually will not benefit from it.^{19,23}

The side-effects of radiation exposure (14): There is a measurable increase in breast cancer due to radiation exposure, though there is no doubt that the benefit of screening is higher. In patients aged 60 and below, there will be one cancer caused by screening radiation in every 2000 cancers identified through mammography screening.^{25,26} But it is important to remember that an increase in radiation damage may also be caused by unnecessary therapeutic radiation due to over diagnosis (see above).²⁴

Recommendations to carry out breast self-examination—BSE (15) is held in high esteem. It remains unproven that breast self-examination can lower the likelihood of dying from breast cancer, it may even lead to an increase in false-positive results

and consequently to an increase in unnecessary interventions.^{7,26} This is why any reference to BSE in brochures must receive a negative evaluation.

Rating

The rating of the brochures was carried out by four researchers from different countries who used a variety of first languages. So we agreed to use the official brochure from England²⁷ as a standard for our rating system. The individual ratings given to the English leaflet by the four assessors showed no substantial differences. In 13 of the 15 items, evaluated general agreement was reached by the four rates. In the two items where ratings varied among the four researchers (information on 'sensitivity' and 'specificity'), we found an operational definition which allowed for identical rating.

Each of the four researchers rated the brochure(s) of his/her own native language. (EG, German; GP, Italian; CO, Spanish; CO, French).

The 15 defined rating criteria listed above were checked if (i) they were present in the brochures and (ii) whether any quantitative data in terms of real numbers (e.g. number of false-positive results, number of saved per screened, etc.) were included.

Results

Overall rating

Of the 14 items defined as essential for making an informed choice, the items included in the brochures ranged from one (Murcia/Spain) to five (Germany, Milano/Italy, Castilla y Leon/Spain). More than half of the listed items were not mentioned in any of the brochures.

Table 1 shows the results of the rating of the brochures in more detail.

The principal finding after analysing the eight brochures is the lack of information about the possible harm caused by mammography screening and no mention of the problems relating to over diagnosis.

Despite the fact that the brochures were written independently of each other in different countries and regions across

Europe, they are in accordance in that they focus only on the benefits of screening. Moreover, each of the eight brochures stress the benefits to women of taking part in the programme (item 1), but only in the brochure from Liguria/Italy was a relative number given to explain the extent of any potential benefit.

The item concerning the reduction of breast cancer mortality rates (item 2) was mentioned in six of the brochures (Madrid, Castilla y Leon, Milano, Liguria, Veneto/Italy and France). The rate of pathological results (item 6) in the screening mammography was explicitly mentioned in four of the brochures (Germany, Madrid, Castilla y Leon, Milano).

The sensitivity of mammography screening (item 9) was mentioned three times (Germany, Castilla y Leon and Milano) in terms of relative numbers, but only once was the correct number provided (Castilla y Leon).

Four of the brochures (Germany, Madrid, Castilla y Leon and Milano) highlighted the possible side-effects of x-ray screening (item 14).

Only the German brochure and two of the Italian ones (Milano and Veneto) stressed the possibility of cancer occurring in the interval between two screening sessions (item 10). The other six brochures mentioned this indirectly by advising on the wisdom of seeing a doctor immediately on feeling something suspicious.

None of the brochures provided information on the number needed to screen (item 4) or the absolute risk reduction (item 3), both of which are useful currencies for describing the results of trials. The rate of false-positive results (item 8) was not mentioned in any brochure, nor was information about test specificity (item 7), issues relating to incorrect diagnosis, treatment that does not benefit the individual (item 13) and the problem of lead-time bias (item 11).

Recommendations for breast self-examination (item 15) were found in four of the brochures (Germany, Castilla y Leon, Milano and Veneto). But as mentioned previously, BSE cannot help to reduce the rate of mortality from breast cancer.²⁶

There were differences in the quality of the brochures. Among the five items mentioned in the German brochure, three concerned the positive effects of screening (benefit,

Table 1 List of criteria essential for informed choice in mammography screening (as mentioned in the brochures)

	Germany	Spain		Italy			France	
		Madrid	Castilla y Leon	Murcia	Milano	Liguria		Veneto
Items mentioned	5	4	5	1	5	3	3	2
Items with data given (RRR only)	0	1	2	0	1	1	0	0
Items with statistically correct data given	0	0	1		1	1		0
1. Benefit	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Reduction of mortality	No	Yes	Yes ^a	No	Yes	Yes ^b	Yes	Yes
3. Absolute risk reduction	No	No	No	No	No	No	No	No
4. NNS	No	No	No	No	No	No	No	No
5. Reduction of total mortality	No	No	No	No	No	No	No	No
6. Rate of pathological result	Yes	Yes ^a	Yes	No	Yes	No	No	No
7. Specificity	No	No	No	No	No	No	No	No
8. Rate of false-positive results	No	No	No	No	No	No	No	No
9. Sensitivity	Yes	No	Yes ^b	No	Yes ^b	No	No	No
10. Interval cancer	Yes	No	No	No	Yes	No	Yes	No
11. Lead time bias	No	No	No	No	No	No	No	No
12. Overdiagnosis—DCIS/early cancer	No	No	No	No	No	No	No	No
13. Increase of surgery and radiotherapy	No	No	No	No	No	No	No	No
14. Side-effects of radiation exposure	Yes	Yes	Yes	No	No	Yes	No	No
15. Recommendation to breast self-examination—BSE	Yes ^c	No	Yes ^c	No	Yes ^c	No	Yes ^c	No

a: Relative numbers mentioned

b: Correct relative numbers

c: It is not proven that BSE can lower the mortality of breast cancer; therefore, a positive result must be valued negatively in these cases

reduction of mortality, sensibility) and two related to the side-effects (interval cancer, radiation risk), but provided no numbers. The findings for the Milanese brochure were similar with five items mentioned, including the issue of interval cancer and a relative number for sensitivity. In the Castillay Leon brochure, five items were found, including actual numbers on sensitivity and reduction of mortality, but no reference to interval cancer was made. In the brochure of Liguria, we found an incorrect number relating to the reduction in rates of mortality, and overall it mentioned only three items. Interval cancer was one of the three items mentioned in the brochure from Veneto. The French brochure only mentioned benefit and reduction in mortality rates but failed to provide any numbers, and the brochure from Murcia contained only one item (benefit). If side-effects were mentioned at all in the brochures, it tended to be interval cancer and radiation risk. Numbers were not exclusively provided in those brochures containing more items.

Excerpts from the brochures

To illustrate the type of statements given in the brochures, we highlighted a few of the passages containing some of the more important items. It is worth mentioning that the citations are the only ones we could find in any of the brochures on specific items, e.g. we did not abridge texts.

Benefit of mammography screening

Madrid: Why is it important to take part? Because the early detection of a possible pathological process can improve the life quality of the affected woman.

Milano: Many studies and several decades of experience have shown that in populations that take part in breast cancer screening the mortality rate of this disease decreases, surgical treatments are reduced, and the long-term treatment outcomes are better.

Reduction of mortality by screening

Liguria: A mammography every 2 years after the age of 50 reduces the probability of death from breast cancer by approximately 30% within 10 years.

Interval cancer

Germany: In rare cases it is possible that breast cancer may appear between two mammography sessions and this can lead to symptoms and discomfort.

Rate of pathological results of screening

Madrid: The results of 90% of mammographies are normal.

Germany: Present experience shows that in 80% of the women who were recalled after a suspicious mammogram, a diagnosis of breast cancer was not confirmed by further analysis.

Breast self-examination - BSE

Veneto: Like every examination it has its limits. Therefore we should continue to assess our breasts regularly between screenings, and consult our doctor if we notice something unusual.

Germany: In the two-year interval between invitations you should watch for any changes in your breasts, such as: Palpable lumps, dents or induration of the skin,

deformation, retraction of the nipple, bleeding or other discharge from the nipple.

Possible side-effects of radiation exposure

Liguria: The dose of radiation absorbed at mammography is low and can be estimated with reasonable certainty.

Some of the pamphlets explicitly encourage participation by using suggestive phrases: 'Ten minutes to save your life' (Liguria), or 'We therefore propose carrying out a mammography, which is safe, bearable and very effective' (Milano). The French pamphlet shows four attractive women with the line: 'They're taking part—what about you?' These phrases are part of an attempt to directly influence women's decision-making and can induce feelings of guilt in those who would rather not take part, as opposed to providing a 'free choice'.

Discussion

Information pamphlets play an important role in public education and influence public perception of a programme. Recently this was demonstrated by a study carried out in several European countries and in the United States, whereby because of an inaccurate demonstration which referred to a 20% reduction in mortality rates as a result of mammography screening, women wrongly concluded that 200 from 1000 women benefit from the programme.¹⁵ Informed consent is not possible without the application of correct and comprehensible numbers and statements; the framing of the message should not be manipulative.

The brochures we analysed do not provide information about the most important harmful side-effects of mammography screening. Above all we could find no information about overdiagnosis, which is the most significant and damaging side-effect of mammography screening. It can lead to an increase in unnecessary surgery, chemotherapy and radiotherapy with all the harmful effects they entail.

Useful data on the benefits were not provided in the majority of the brochures analysed, which makes it reasonable to assume that the small ARR, and consequent high NNS, was the reason for this deficit.

We found some variations in the quality of the brochures in Germany, Italy, Spain and France. However even the high-range brochures in our analysis did not receive higher ratings than those brochures analysed 2–3 years ago.^{7,10,12}

The few comparable studies carried out up to now on the subject of mammography information brochures show that none of the brochures being analysed give balanced information on the benefits and risks of screening, and are usually of only limited value to women when deciding whether to attend a screening or not.^{6,8} In general the previous studies were carried out along similar lines to our own study: the pamphlets of a particular country—or in the case of the study by Jørgensen and Goetzsche⁷ of countries speaking languages the authors could understand—were evaluated using a checklist developed to verify the nature of the information being provided to women. The number of items relating to benefits and risks varies. Joergensen and Goetzsche⁷ used 17 items, Giordano (Italy) *et al.*¹⁰ more than 36 and Zapka (USA)⁹ only five items. The results of these studies and our own—achieved some 3–5 years later and in countries with very different medical cultures—show a remarkable level of agreement. All the brochures focus on practical advice, highlighting the benefits of screening in relative numbers, but lack information about risks and side-effects. In particular the major risk of screening,

i.e. overdiagnosis and subsequent overtreatment, is not mentioned in any of the brochures.

Besides concealing important information, our study found that the brochures also attempt to directly influence women with suggestive phrases to pressurize into participation. The brochures tend to focus on public health issues rather than on any potential benefits for the individual participant.

This implicit emphasis became explicit in Germany when a law was passed which economically punishes those abstaining from cancer screening who subsequently develop a cancer of any type for which a screening programme is in place.

It should be pointed out that this law has been modified towards an obligation to seek counsel from a doctor.

Conclusions

Our results imply that the providers of mammography screening programmes in Germany, Italy, Spain and France conceal essential information from women needed to make an informed choice. This is also the impression gained from the analyses of other brochures from other countries.

It is fair to assume that the reason the brochures are of such low quality and have failed to improve over the years is a result of an implicit decision to take a public health perspective on these matters, rather than the personalized perspective of those being invited. The mammography programmes can only be cost-effective (high overhead costs) when used by a certain percentage of those invited. Usually a percentage of 70% is seen as necessary. To reach this percentage it is necessary to convince women to participate and it may even be counter-productive to include all the information at the experts' disposal. Low ARR or high NNS and any reference to the possible side-effects, including most significantly overdiagnosis, could dissuade a substantial number of women from taking part. The public health effect of screening would begin to decline.

We therefore assume that the providers of mammography-screening programmes are fearful that better and more comprehensive information would lead to lower participation rates.

Limitations

The inter-rater agreement of the assessors was only assessed once, using a reference pamphlet.²⁷ In an ideal world, each assessor would have rated every one of the analysed pamphlets. For pragmatic purposes, we decided that one rate per pamphlet was acceptable, as the rating of the reference brochure showed such a high level of consistency across all the assessors. Therefore, we do not know the precise inter-rater agreement. However, we are confident that the main study results are not affected by this limitation.

As a result of our decision to use a rating system that had been developed previously, for better comparison with the prior study, we also adopted the criteria used there.⁷

We only took a selection of brochures from Spain and Italy, because there are only regional programmes in these countries and these contain different information structures. Because we chose just three regions, the study is not representative for the whole of Italy and Spain.

Conflict of interest: None declared.

Key points

- Former studies showed that information brochures on mammography screening in the UK and Scandinavia do not provide necessary information for an informed consent.
- We expanded this analysis to brochures from countries with a different medical culture, i.e. Germany, Italy, Spain and France.
- We found out that brochures from there do not contain any more information.
- Brochures follow an implicit public health orientation of these programmes, not the personal perspective that a woman is expecting when being invited.

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Appendix I

- Zentrale Stelle Mammographie Screening (Deutschland). Programm zur Früherkennung von Brustkrebs für Frauen zwischen 50 und 69 Jahre